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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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GOVERNMENT EMPLOYEES INSURANCE COMPANY, GEICO INDEMNITY COMPANY, GEICO GENERAL INSURANCE COMPANY and GEICO CASUALTY COMPANY,

Docket No.: _____( )

Plaintiffs,

-against-

SMK PHARMACY CORP. d/b/a NATURE'S FIRST LONG TERM CARE AND COMPOUNDING, ALEXANDER BURLAK, MARC KASSMAN, KIM VOLMAN, SIMON FIELD, AND JOHN DOE NOS. "1" THROUGH "5",

Defendants.
----------X

COMPLAINT

Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company, and GEICO Casualty Company (collectively "GEICO" or "Plaintiffs"), as and for their Complaint against Defendants SMK Pharmacy Corp. d/b/a Nature's First Long Term Care and Compounding, Alexander Burlak, Marc Kassman, Kim Volman, Simon Field, and John Doe Nos. "1" through "5" (collectively, "Defendants"), hereby allege as follows:

1. This action seeks to terminate a massive fraudulent scheme perpetrated against GEICO by the Defendants who have exploited the New York "No-Fault" insurance system by submitting more than $4,023,200.00 in fraudulent pharmaceutical billing to GEICO. Specifically, the Defendants submitted, or caused to be submitted, thousands of fraudulent charges seeking payment for medically unnecessary "pain relieving" prescription drug products, including topical compounded pain creams, topical pain gels and ointments, and topical pain patches, (collectively, the "Fraudulent Topical Pain Products"), as well as various other prescription drug medications (together with the Fraudulent Topical Pain Products, the "Fraudulent Pharmaceuticals").

2. Defendants SMK Pharmacy, Corp. d/b/a Nature's First Long Term Care and Compounding ("SMK Pharmacy") and its owners, Alexander Burlak ("Burlak"), Marc Kassman ("Kassman"), Kim Volman ("Volman"), and Simon Field ("Field") dispensed the Fraudulent Pharmaceuticals to individuals involved in automobile accidents and eligible for insurance coverage under policies of insurance issued by GEICO (the "Insureds"). As part of the fraudulent scheme, the Defendants colluded with various prescribing healthcare providers (the "Prescribing Providers") and unlicensed laypersons ("Clinic Controllers") who work at or are associated with various multidisciplinary medical clinics that almost exclusively treat No-Fault patients ("No-Fault Clinics"). Pursuant to these collusive arrangements, the Defendants steered the Prescribing Providers and Clinic Controllers to prescribe large volumes of boilerplate, formulaic, and medically unnecessary prescriptions for the Fraudulent Pharmaceuticals -- often using rubber stamps or labels supplied to them by the Defendants -- that were directed to SMK Pharmacy in exchange for kickbacks.

3. To effectuate the scheme and maximize profits, the Defendants intentionally targeted a handful of specific topical pain medications (i.e., the Fraudulent Topical Pain Products)

to dispense to Insureds based solely on the medications' exorbitant pricing and high profit margins. The Fraudulent Topical Pain Products dispensed and billed for included topical compounded drug products (the "Fraudulent Compounded Pain Creams"), which are not approved by the United States Food and Drug Administration ("FDA") and have no proven efficacy. Rather, the compounded drugs were created by the Defendants by combining multiple expensive drugs to inflate the amounts they could charge, which they then dispensed in systematic fashion in violation of state and federal licensing requirements designed to ensure the quality, safety, and effectiveness of compounded drug products.

4. The scheme by the Defendants to steer the Prescribing Providers and Clinic Controllers to routinely prescribe large volumes of the Fraudulent Topical Pain Products to Insureds and route those prescriptions to SMK Pharmacy egregiously inflated the charges submitted to GEICO. For example, the Defendants typically billed between $803.09 and $855.26 for a single tube of Fraudulent Compounded Pain Cream, although charges at times exceeded $1,200.00 for a single tube. Similarly, the Defendants typically billed between $909.89 and $948.59 for a single diclofenac sodium 3% transdermal gel ("Diclofenac Gel") prescription; between $212.59 and $1,108.69 for a single diclofenac sodium 1.5% solution ("Diclofenac Solution") prescription; between $308.49 and $613.89 for a single lidocaine 5% ointment ("Lidocaine 5% Ointment") prescription; and between $229.69 and $903.59 for a single lidocaine 5% patch ("Lidocaine Patch") prescription.

5. The Defendants' scheme not only inflated the charges to insurers, but also posed serious risks to the patients' health, safety, and well-being, as the Fraudulent Topical Pain Products were prescribed and dispensed without regard to genuine patient care, without regard to proper

documentation by the Prescribing Providers, and often in violation of state and federal licensing requirements.

6. By this action, GEICO seeks to recover more than $1,184,700.00 that the Defendants stole from it, along with a declaration that GEICO is not legally obligated to pay reimbursement to SMK Pharmacy of over $1,926,600.00 in pending fraudulent No-Fault claims that the Defendants submitted or caused to be submitted through SMK Pharmacy because:

(i) SMK Pharmacy billed for pharmaceutical products that were medically unnecessary and prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit patients for financial gain, without regard for genuine patient care;

(ii) The Defendants participated in illegal, collusive relationships in which they steered the Prescribing Providers and Clinic Controllers to direct illegal prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy in exchange for unlawful kickbacks and other financial incentives;

(iii) the Defendants intentionally targeted a specific set of pharmaceutical products (i.e., the Fraudulent Topical Pain Products) that they acquired at low cost and dispensed to Insureds through SMK Pharmacy in large volumes at egregious charges, in place of other effective, less costly pharmaceuticals;

(iv) the Defendants engaged in illegal bulk compounding by having SMK Pharmacy specialize in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements, rendering it ineligible to receive reimbursement for No-Fault benefits; and

(v) the Defendants made and continue to make false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for the Fraudulent Pharmaceuticals under the name of SMK Pharmacy pursuant to illegal, invalid, duplicitous, and formulaic prescriptions.

7. The Defendants fall into the following categories:

(i) SMK Pharmacy is a New York corporation that engaged in a fraudulent scheme in which it produced and dispensed in bulk, pursuant to illegal, collusive agreements, the Fraudulent Topical Pain Products to patients and

then submitted bills to GEICO and other New York automobile insurers for reimbursement to which it is not entitled;

(ii) Burlak, Kassman, Volman, and Field are purported owners of SMK Pharmacy;

(iii) John Doe Defendants "1" through " 5" are persons and entities, presently not identifiable, who are not and never have been licensed healthcare professionals but who, along with Burlak, Kassman, Volman, and Field, participated in the operation and control of SMK Pharmacy, facilitated the illegal, collusive relationships with SMK Pharmacy, and otherwise knowingly participated in the fraudulent scheme described in the Complaint.

8. The Defendants' scheme began in 2017 and has continued uninterrupted to the present day. As discussed more fully below, the Defendants at all times have known that: (i) SMK Pharmacy billed for pharmaceutical products that were medically unnecessary and prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit patients for financial gain, without regard for genuine patient care; (ii) the Defendants participated in illegal, collusive relationships in which the Defendants solicited and received illegal prescriptions for the Fraudulent Pharmaceuticals from the Prescribing Providers and Clinic Controllers in exchange for unlawful kickbacks and other financial incentives; (iii) the Defendants intentionally targeted a specific set of pharmaceutical products (i.e., the Fraudulent Topical Pain Products) that they acquired at low cost and, through SMK Pharmacy, dispensed in large volumes to Insureds at egregious charges, in place of other effective, less costly pharmaceuticals; (iv) the Defendants engaged in illegal bulk compounding by having SMK Pharmacy specialize in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements; and (v) the Defendants made and continue to make false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for the Fraudulent Pharmaceuticals under the name of SMK Pharmacy pursuant to illegal, duplicitous, and formulaic prescriptions.

9. Based on the foregoing, SMK Pharmacy does not now have – and has never had – any right to be compensated for the Fraudulent Topical Pain Products allegedly dispensed to GEICO Insureds. The chart attached hereto as Exhibit "1" sets forth a sample of the fraudulent claims that have been identified to date which the Defendants submitted, or caused to be submitted, to GEICO through the United States mail. As a result of the Defendants' scheme, GEICO has incurred damages of approximately $1,184,700.00.

THE PARTIES

I. Plaintiffs

10. Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company are Nebraska corporations with their principal places of business in Chevy Chase, Maryland. GEICO is authorized to conduct business and to issue automobile insurance policies in New York.

II. Defendants

11. Defendant SMK Pharmacy is a New York corporation, incorporated on or about July 12, 2005, with its principal place of business at 8702 Rockaway Beach Blvd, Rockaway Beach, New York.

12. SMK Pharmacy, through the present day, has knowingly submitted fraudulent claims to GEICO and continues to seek reimbursement on unpaid fraudulent claims.

13. SMK Pharmacy engages in bulk pharmaceutical compounding activities and specializes in producing and dispensing compounded pain creams.

14. SMK Pharmacy is registered with New York State as a pharmacy but not as a manufacturer or outsourcing facility.

15. SMK Pharmacy is not permitted to engage in bulk compounding or specialize in dispensing large quantities of compounded pain creams that are not specially tailored to the needs of individual patients.

16. Defendant Burlak resides in and is a citizen of New York. Burlak was licensed to practice pharmacy in New York on September 2, 2010 and dispensed many of the Fraudulent Topical Pain Products billed to GEICO and other insurers through SMK Pharmacy. Burlak is an owner of SMK Pharmacy and is listed with the New York State Office of the Professions as the supervising pharmacist for SMK Pharmacy.

17. Defendant Kassman resides in and is a citizen of New York. Kassman, was licensed to practice pharmacy in New York on July 31, 1997 and dispensed many of the Fraudulent Topical Pain Products billed to GEICO and other insurers through SMK Pharmacy. Kassman is as an owner of record and vice president of SMK Pharmacy.

18. Defendant Volman resides in and is a citizen of New York. Volman was licensed to practice pharmacy in New York on November 14, 2001. Upon information and belief, Volman is an owner of SMK Pharmacy. This belief is based upon the fact that Volman signed the Certification of Incorporation as Incorporator for SMK Pharmacy and filed the Certificate of Incorporation with New York State, and the fact that Defendant Burlak identified Volman to GEICO as having an ownership interest in SMK Pharmacy.

19. Defendant Field resides in and is a citizen of New York. Field was licensed to practice pharmacy in New York on July 31, 1997. Upon information and belief, Field is an owner of SMK Pharmacy. This belief is based upon the fact that public records identify Field as the president of SMK Pharmacy, and the fact that Defendant Burlak identified Field to GEICO as having an ownership interest in SMK Pharmacy.

20. John Doe Defendants "1" through " 5", upon information and belief, reside in and are citizens of New York, and are persons and entities, presently not identifiable, who are not and never have been licensed healthcare professionals but who, along with Burlak, Kassman, Volman, and Field, participated in the operation and control of SMK Pharmacy, facilitated the illegal, collusive relationships with SMK Pharmacy, and otherwise knowingly participated in the fraudulent scheme described in the Complaint.

JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between citizens of different states.

22. Pursuant to 28 U.S.C. § 1331, this Court also has jurisdiction over the claims brought under 18 U.S.C. §§ 1961 et seq., the Racketeer Influenced and Corrupt Organizations ("RICO") Act, because they arise under the laws of the United States.

23. In addition, this Court has supplemental jurisdiction over the subject matter of the claims asserted in this action pursuant to 28 U.S.C. § 1367.

24. Venue in this District is appropriate pursuant to 28 U.S.C. § 1391, as the Eastern District of New York is the District where one or more of the Defendants reside and because this is the District where a substantial amount of the activities forming the basis of the Complaint occurred.

ALLEGATIONS COMMON TO ALL CLAIMS

25. GEICO underwrites automobile insurance in the State of New York.

I. An Overview of New York's No-Fault Laws

26. New York's "No-Fault" laws are designed to ensure that injured victims of motor

vehicle accidents have an efficient mechanism to pay for and receive the healthcare services that they need. Under New York's Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law §§5101 et seq.) and the regulations promulgated pursuant thereto (11 N.Y.C.R.R. §§65 et seq.)(collectively referred to herein as the "No-Fault Laws"), automobile insurers are required to provide Personal Injury Protection Benefits ("No-Fault Benefits") to Insureds.

27. No-Fault Benefits include up to $50,000.00 per Insured for necessary expenses that are incurred for health care goods and services.

28. The No-Fault Laws limit reimbursement for benefits to prescription drugs only. Over-the-counter ("OTC") drugs and products which may be purchased without a prescription are not covered expenses under the No-Fault Laws.

29. An Insured can assign his or her right to No-Fault Benefits to the providers of healthcare services in exchange for those services. Pursuant to a duly executed assignment, a healthcare provider may submit claims directly to an insurance company and receive payment for necessary goods and medical services provided, using the claim form required by the New York State Department of Insurance (known as the "Verification of Treatment by Attending Physician or Other Provider of Health Service," or, more commonly, as an "NF-3"). In the alternative, healthcare providers sometimes submit claims using the Health Care Financing Administration insurance claim form (known as the "HCFA-1500 Form").

30. Pursuant to New York's No-Fault Laws (11 N.Y.C.R.R. § 65-3.16(a)(12)), a healthcare provider is not eligible to receive No-Fault Benefits if it fails to meet any applicable New York state or local licensing requirement necessary to perform such services in New York.

31. The implementing regulation adopted by the Superintendent of Insurance, 11 NYCRR § 65-3.16(a)(12), provides, in pertinent part, as follows:

> A provider of health care services is not eligible for reimbursement under section 5102(a)(1) of the Insurance Law if the provider fails to meet any applicable New York State or local licensing requirement necessary to perform such service in New York … (emphasis supplied).

32. In State Farm Mut. Auto. Ins. Co. v. Mallela, 4 N.Y.3d 313 (2005), the New York Court of Appeals made clear that healthcare providers who fail to comply with licensing requirements are ineligible to collect No-Fault Benefits, and that insurers may look beyond a facially valid license to determine whether there was a failure to abide by state and local law.

33. Pursuant to New York Insurance Law §403, the NF-3s and HCFA-1500 Forms submitted by a healthcare provider to GEICO, and to all other automobile insurers, must be verified by the health care provider subject to the following warning:

> Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

II. An Overview of Applicable Licensing Laws

34. Pursuant to New York Education Law §6808, no person or entity shall possess drugs for the purpose of compounding, dispensing, retailing, wholesaling, or manufacturing, or shall offer drugs for sale unless registered by the New York State Department of Education as a pharmacy, wholesaler, manufacturer, or outsourcing facility.

35. Pursuant to 8 N.Y.C.R.R. § 29.1, pharmacies in New York are prohibited from "exercising undue influence on the patient or client, including the promotion of the sale of services, goods, appliances or drugs in such manner as to exploit the patient or client for the financial gain of the practitioner or of a third party."

36. Similarly, 8 N.Y.C.R.R. § 29.1 prohibits pharmacies from "directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or

from a third party for the referral of a patient or client or in connection with the performance of professional services."

37. Pursuant to 8 N.Y.C.R.R. § 63.1(7), pharmacists or pharmacy interns shall conduct a prospective drug review before each prescription is dispensed, which review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-drug interactions, including serious interactions with over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

38. New York Education Law §6530(38) prohibits a licensed physician from entering into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions, while New York Education Law §6811 makes it a crime for any person to enter into an agreement with a physician (or other licensed healthcare provider) for the compounding or dispensing of secret formula ("coded") prescriptions.

39. New York Education Law §6530(18) prohibits a licensed physician from "directly or indirectly" offering, giving, soliciting, receiving, or agreeing to receive any fee or other consideration to or from a third party in exchange for patient referrals or in connection with the performance of professional services.

40. New York Education Law §6509-a, prohibits a professional licensee from "directly or indirectly" requesting, receiving, or participating in the division, transference, assignment, rebate, splitting, or refunding of a fee in connection with professional care or services including services related to drugs and/or medications.

41. New York Education Law § 6810 prohibits pharmacies from dispensing a drug when the prescription form for that drug includes any other drug. Separate prescriptions are required for each drug prescribed and dispensed.

42. New York Education Law § 6810 prohibits persons and corporations, not licensed to issue a prescription, to willfully cause prescription forms, blanks, or facsimiles thereof to be disseminated to any person other than a person who is licensed to issue a prescription.

III. An Overview of Compounded Drug Products

43. The United States Federal Food, Drug, and Cosmetic Act ("FDCA") authorizes the United States Food and Drug Administration ("FDA") to oversee the safety of food, drugs, and cosmetics.

44. The FDA strictly regulates OTC and prescription drugs, and oversees drug manufacturing in several ways, including testing drugs and routinely inspecting drug manufacturing plants and outsourcing facilities engaged in the compounding of drugs.

45. FDA-approved drugs require: (i) approval prior to marketing; (ii) compliance with federal labelling laws; and (iii) that the drugs be made and tested in accordance with good manufacturing practice regulations (GMPs), which are federal statutes that govern the production and testing of pharmaceutical products.

46. Compounded drugs are not FDA-approved, though they may contain FDA-approved drugs, and are generally exempt from the FDA approval process which applies to new drugs – but only under limited circumstances. See 21 U.S.C. § 353a.

47. In particular, pursuant to Section 503A of the FDCA, as amended by the Compounding Quality Act, the laws applicable to drugs regulated by the FDA, including the laws relating to the safe manufacturing of drugs, generally do not apply to a "compounded" drug product: (1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order that a compounded product is necessary for the identified

patient, and (2) if the compounding is performed by a licensed pharmacist in a state licensed pharmacy.

48. Unlike FDA-approved products, consumers and prescribers cannot assume that compounded drugs were made by validated processes in properly calibrated and cleaned equipment; that the ingredients in the drug were obtained from FDA-approved sources; that production personnel had the requisite knowledge and training; and that appropriate laboratory testing was performed to verify the compounded drug's potency, purity, quality, and safety.

49. The FDA has publicly expressed concern regarding large-scale drug manufacturing under the guise of traditional small-scale pharmacy compounding. For example, the FDA has noted that poor practices on the part of bulk drug compounders can result in contamination or products that do not possess the strength, quality, and purity required. Published reports also consistently show that compounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs.

50. Traditional pharmacy compounding by state licensed pharmacies, therefore, is permissible when done on a small scale by pharmacists who prepare the medication based on an individual prescription. Specifically, when compounded drugs meet the requirements of 21 U.S.C. § 353a and are compounded to meet the particular needs of an individual patient, they can be exempted from the requirement, among others, that they be FDA-approved. See 21 U.S.C. § 355(a).

51. When Congress adopted 21 U.S.C. § 353a, its express intent was to permit compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing [of drugs that would otherwise require FDA

approval] under the guise of compounding." H.R. Rep. No. 105-399, at 94 (1997) (Conf. Rep.)(emphasis added). As Congress stated at the time:

> The "exemptions in [this section] are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compound. To qualify for the exemptions, the pharmacist or physician must be able to cite to a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate. Although recording the medical need directly on each prescription order would not be required, this technique would be one of many acceptable ways of documenting the medical need for each compounded drug product. This medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons. The pharmacist may rely on appropriately documented input from the physician as to whether a commercially available drug product is not appropriate for the identified individual patient.

S. Rep. No. 105-43, at 67-68 (1997) (emphasis added).

52. The prescription of compounded drug products and ensuing billing to both private and public insurers has been the subject of state and federal investigations and litigation due to increased concerns regarding fraud.

53. The U.S. Department of Health & Human Services and the U.S. Postal Service have both issued reports documenting fraud concerns with compounded drugs. See High Part D Spending on Opioids and Substantial Growth in Compound Drugs Raise Concerns, HHS OIG Data Brief, OEI-16-00290 (June 2016); Worker's Compensation Compound Drug Costs, Management Advisory, Report No. HR-MA-16-003 (March 14, 2016). Most recently, the U.S. Department of Health issued a report which noted that many pharmacies in New York State are among the most questionable in the nation. See Questionable Billing For Compounded Topical Drugs in Medicare Part D, OEI-02-16-00440 (August 2018)

54. Further, there have been numerous criminal proceedings commenced in connection with compounded drug products. For example:

- in January 2014, the United States Attorney for the District of New Jersey obtained a guilty plea from a pharmacist involved in the payment of

kickbacks to a physician in exchange for prescriptions for compounded pain creams. See USA v. Kleyman, 1:14-CR-598-JHR, Docket No. 1;

- in February 2016, the United States Attorney for the Northern District of Texas indicted two laypersons who conspired with physicians and pharmacies in a scheme involving producing, prescribing, and distributing compounded creams, including payment of kickbacks to prescribing physicians and insured beneficiaries. See USA v. Cesario, 3:16-CR-060-M, Docket Nos. 3, 75;

- in June 2016, the United States Attorney for the Middle District of Florida indicted a physician for a fraudulent scheme involving payment of kickbacks for the referral of patients and prescriptions for compounded creams. See USA v. Baldizzi, 8:16-CR-271-MSS-AEP, Docket No. 1;

- in August 2016, the United States Attorney for the Southern District of New York indicted members of the Genovese, Gambino, Luchese, and Bonanno crime families, whose alleged illegal activities included "causing…corrupt doctors to issue unnecessary and excessive prescriptions for expensive compound creams" billed to insurers. See USA v. Parrello, 16 Crim. 522 (2016); and

- in 2020, the United States Attorney for the Central District of California indicted three laypersons and one physician for their involvement in a $22 million fraudulent scheme in which they paid kickbacks in exchange for large volumes of fraudulently generated prescriptions for compounded pain creams. See USA v. Bell, 8:20-CR-00018-JVS, Docket No. 1.

IV. The Defendants' Scheme Involving The Fraudulent Topical Pain Products

A. Overview of the Scheme

55. Beginning in 2017, and continuing uninterrupted through the present day, the Defendants masterminded and implemented a fraudulent scheme in which they used SMK Pharmacy to bill the New York automobile insurance industry for millions of dollars in inflated charges – which they were not eligible to receive – for the Fraudulent Topical Pain Products purportedly provided to patients involved in automobile accidents.

56. As part of the Defendants' fraudulent scheme, they steered prescriptions for the Fraudulent Topical Pain Products to SMK Pharmacy by paying unlawful kickbacks or providing

financial incentives or other forms of compensation to the Prescribing Providers and/or to the Clinic

57. In keeping with the fact that Prescribing Providers and Clinic Controllers steered prescriptions to SMK Pharmacy pursuant illegal, collusive arrangements, the Defendants provided the Prescribing Providers with rubber stamps or preprinted labels that contained the names and ingredients of the Fraudulent Topical Pain Products that were created, produced, and/or dispensed by SMK Pharmacy, including the "coded" names of Fraudulent Compounded Pain Creams and the predetermined formulations of those creams.

58. The Fraudulent Topical Pain Products were designed to exploit the Insureds for financial gain, as they typically were prescribed based on generic, preprinted, and boilerplate examination reports designed to justify continuing, voluminous, and excessive healthcare services.

59. Indeed, there was no legitimate justification for the fact that Prescribing Providers and Clinic Controllers steered prescriptions to SMK Pharmacy since the Fraudulent Topical Pain Products themselves often have no proven efficacy and were often duplicative of other medications contemporaneously prescribed and dispensed to the Insureds.

60. Further, the Fraudulent Compounded Pain Creams were almost never prescribed properly in accordance with governing state and federal regulations.

61. In addition, the Prescribing Providers never gave the prescriptions directly to the Insureds to fill (even though they issued paper rather than electronic prescriptions) and did not give the Insureds the option to use a pharmacy of their choosing.

62. Rather, the Prescribing Providers directed the prescriptions for the Fraudulent Topical Pain Products to SMK Pharmacy, notwithstanding that in many instances the No-Fault

Clinics and the patients' residences were located far from SMK Pharmacy and there were countless other pharmacies located much closer to the No-Fault Clinics and the patients.

63. In fact, virtually none of the GEICO Insureds who were purportedly dispensed Fraudulent Topical Pain Products by SMK Pharmacy live in Rockaway Beach, Queens, where SMK Pharmacy is located, and only 18% of Insureds live anywhere in Queens County.

64. The Prescribing Providers and Clinic Controllers directed and steered the prescriptions for the Fraudulent Topical Pain Products to SMK Pharmacy without regard for any legitimate concern for the patient because the prescriptions were issued pursuant to the illegal, collusive arrangements among the Defendants, the Prescribing Providers, and the Clinic Controllers.

B. The Fraudulent Topical Pain Products Were Prescribed and Dispensed Without Regard to Genuine Patient Care

65. In basic terms, the goal of medical treatment is to help patients get better in a timely manner. Notwithstanding this basic goal, the Insureds treated by the Prescribing Providers were virtually always subjected to a predetermined and unnecessarily prolonged treatment protocol, which completely lacked in individualized care and failed to utilize evidence-based medical practices with the goal of the Insureds' timely return to good health.

66. Evidence-based best practice guidelines for the treatment of acute and chronic pain do exist and should always guide prescribing habits. For example, the World Health Organization ("WHO") pain relief ladder recommends a non-opioid such as acetaminophen or a non-steroidal anti-inflammatory drug ("NSAID") for the initial management of pain. NSAIDs are the most commonly prescribed analgesic medications worldwide, and their efficacy for treating acute pain has been well demonstrated. If pain relief is not achieved, and doses are maximized, then an adjuvant oral agent may be added to the medication regimen – including the use of muscle relaxers

and medications that block neuropathic pain transmission. Finally, opiates may be prescribed for short-term, limited use.

67. Clinical studies of FDA-approved topical NSAIDs have shown them to be no more effective than placebo for treating acute pain (e.g., strains, sprains, contusions, or overuse injuries) in superficial locations.

68. More recently, in 2019 the Department of Health & Human Services ("DHHS") issued a Pain Management Best Practices Inter-Agency Task Force Report which focused on pain management and the treatment of acute and chronic pain. According to the DHHS report, such pain should be treated using an individualized, multimodal approach which may include prescription medications depending on various biological, psychological, and social factors of an individual patient, including, but not limited to, a patient's age, medical history, pain tolerance, genetics and neurological factors, stress level, coping ability, social support, and even education and cultural factors. A risk-benefit analysis should be applied to each patient prior to determining whether a medication is clinically appropriate. Like the WHO pain relief ladder, the DHHS report indicates that non-opioids (e.g., NSAIDs) should be used as first line therapy for patients for whom medications are clinically appropriate.

69. Despite these guidelines and the basic goal of helping patients get better in a timely fashion, the Prescribing Providers' treatment reports almost uniformly reflected that the Insureds did not get better, did not return to good health, and/or did not experience improvement in their conditions such that the Insureds could terminate medical treatment expeditiously and return to normal activity.

70. Instead, the Prescribing Providers produced generic, preprinted, and boilerplate examination reports designed to justify continued, voluminous, and excessive healthcare services

that the healthcare providers at the No-Fault Clinics purported to render to Insureds as part of a predetermined protocol that failed to include any individualized treatment whatsoever. These healthcare services included the prescription of excessive and medically unnecessary pharmaceutical drug products such as the Fraudulent Topical Pain Products dispensed by SMK Pharmacy.

71. Notably, the Prescribing Providers often failed to document a detailed medical history of the patients to whom they prescribed the Fraudulent Pharmaceuticals. Alternatively, the Prescribing Providers inaccurately documented the patients' medical histories, including any current medications the patients were taking at the time of the examination.

72. Prescribing a multitude of pharmaceutical drug products without first taking a detailed, and accurate, patient history demonstrates a gross indifference to patient health and safety as the Prescribing Providers often do not know whether the patient is currently taking any medication or suffering from any comorbidity that would contraindicate the use of a particular prescribed drug.

73. Notwithstanding the creation of the examination reports, the Prescribing Providers' prescriptions for the Fraudulent Topical Pain Products dispensed by SMK Pharmacy were based on predetermined protocols, designed to exploit the Insureds for financial gain, without regard to the genuine needs of the patients, and with gross indifference to patient health and safety.

74. The prescriptions routinely authorized by the Prescribing Providers primarily included exorbitantly priced topical pain products, including Fraudulent Compounded Pain Creams, Diclofenac Gels, Diclofenac Solutions, Lidocaine 5% Ointments, and Lidocaine Patches.

75. Notably, for a drug to alleviate pain it must reach nerve or tissue receptors responsible for producing or transmitting a person's sensation of pain.

76. Oral pain relievers reduce or alleviate pain by entering the bloodstream through the gastrointestinal system and traveling to the relevant nerve or tissue receptors. Some of the limited circumstances in which a physician would prescribe a topical medication include patients in whom these oral medications are contraindicated. For example, patients with moderate to severe kidney or liver dysfunction, or those with comorbidities that preclude the use of oral NSAIDs (e.g., history of peptic ulcer disease, coronary artery disease, or congestive heart failure).

77. Despite this, the Prescribing Providers virtually never documented in their examination reports whether oral medications were contraindicated for a particular patient.

78. The Prescribing Providers also did not document in their examination reports the reasons why the Fraudulent Topical Pain Products prescribed were medically necessary.

79. The Prescribing Providers also continuously failed to document in their follow-up examination reports whether the Fraudulent Topical Pain Products prescribed to a particular patient were used by the patient.

80. The Prescribing Providers also continuously failed to document in their follow-up examination reports whether the Fraudulent Topical Pain Products provided any pain relief to the patient or were otherwise effective for the purpose prescribed.

81. At times, the Prescribing Providers failed to document in any of their examination reports that the patient even received a Fraudulent Pharmaceutical.

82. The Prescribing Providers' failure to properly document which Fraudulent Pharmaceuticals were prescribed to their patients and the patients' reactions to those pharmaceuticals demonstrates a complete disregard for patient health and safety.

83. In addition, the Prescribing Providers often recommended Insureds continue taking oral NSAIDs (e.g., ibuprofen and naproxen) and/or prescribed oral NSAIDs contemporaneous to

prescribing Fraudulent Topical Pain Products containing NSAIDS, which is known as therapeutic duplication. Therapeutic duplication can cause adverse events to the patient and very often leads to emergency room visits because the use of more than one medication in the same class of drugs exacerbates the possible adverse side effects.

84. Each year in the United States, approximately 4.5 million ambulatory care visits and 100,000 deaths occur because of adverse drug reactions. A substantial number of these adverse drug reactions are the result of improper prescription practices associated with therapeutic duplication. See, Mathew Witry, PharmD, PhD, Medication List Discrepancies and Therapeutic Duplications Among Dual Use Veterans, Federal Practitioner, 14 (September 2016).

85. The Defendants further failed to perform any legitimate prospective drug review regarding therapeutic duplication, drug-drug interactions, duration of drug treatment, or clinical abuse or misuse before dispensing the Fraudulent Topical Pain Products to Insureds.

C. The Fraudulent Compounded Pain Cream Prescriptions

86. As part of their fraudulent, profit-driven scheme, the Defendants submitted or caused to be submitted, hundreds of thousands of dollars in claims for medically unnecessary Fraudulent Compounded Pain Creams under the name of SMK Pharmacy.

87. The FDA defines traditional pharmacy compounding as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. Traditional pharmacy compounding plays a role in providing access to medications for patients with unique medical needs, which cannot otherwise be met with a commercially available product. State licensed pharmacies may compound specified medications when an FDA-approved drug product is not available or appropriate for a patient, including strength or route of delivery.

88. Compounded products are not FDA-approved, and therefore, not subject to FDA regulations regarding quality, safety, and effectiveness of manufactured drug products.

89. Because compounded products are not FDA-approved, and therefore, not subject to FDA regulations regarding quality, safety, and effectiveness of manufactured drug products, they should never be prescribed as a matter of routine therapy, and should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed.

90. SMK Pharmacy dispensed the Fraudulent Compounded Pain Creams, which are not FDA-approved, in predetermined set formulations, without tailoring the medications to the individual needs of an individual patient, and without complying with licensing requirements that are designed to ensure the quality, safety and effectiveness of bulk compounded drug products.

91. SMK Pharmacy intentionally produced and dispensed the Fraudulent Compounded Pain Creams without regard for the absence of any proven efficacy of the combination of ingredients in a topical formulation and did so solely to generate profits.

92. To conceal this fraudulent scheme, SMK Pharmacy produced and dispensed the Fraudulent Compounded Pain Creams while concomitantly dispensing commercially, available, FDA-approved medications including oral NSAIDs and other topical pain medications.

93. The Defendants marketed the Fraudulent Compounded Pain Creams to various No-Fault Clinics that treated thousands of Insureds and solicited the Clinic Controllers and Prescribing Providers to prescribe, or caused to be prescribed, the medically unnecessary and illusory Fraudulent Compounded Pain Creams to Insureds. The Defendants then used those prescriptions to bill GEICO for the Fraudulent Compounded Pain Creams under the name of SMK Pharmacy.

94. In furtherance of the scheme, the Defendants provided the Prescribing Providers and Clinic Controllers with preprinted labels or rubber stamps which contain the coded names and the predetermined ingredients of the Fraudulent Compounded Pain Creams, including the percentage concentrations of each ingredient used. The Defendants provided the Prescribing Providers and Clinic Controllers with preprinted labels and rubber stamps to make it as convenient as possible for them to prescribe, or caused to be prescribed, as many Fraudulent Compounded Pain Creams as possible.

95. The Prescribing Providers then used the preprinted labels or rubber stamps on their official New York State prescription pads to prescribe to Insureds the Fraudulent Compounded Pain Creams, which were then created, produced, and dispensed by the Defendants through SMK Pharmacy. A representative sample of the prescriptions for Fraudulent Compounded Pain Creams using labels or rubber stamps provided to the Prescribing Providers and Clinic Controllers by SMK Pharmacy, and which SMK Pharmacy submitted to GEICO in support of its fraudulent billing, is annexed hereto as Exhibit "2".

96. The Prescribing Providers often recommended Insureds continue taking oral NSAIDs (e.g., ibuprofen and naproxen) or prescribed oral NSAIDs contemporaneous to prescribing Fraudulent Compounded Pain Creams containing at least one NSAID thereby exposing patients to increased risks caused by therapeutic duplication.

97. Similarly, the Prescribing Providers often recommended Insureds continue taking oral muscle relaxers (e.g., cyclobenzaprine, baclofen, and tizanidine) or prescribed oral muscle relaxers contemporaneous to prescribing Fraudulent Compounded Pain Creams containing at least one muscle relaxer, which is also duplication of therapy.

98. Prior to receiving a prescription for any compounded drug product, a patient's medical records should document all other forms of FDA-approved drugs that were prescribed and failed to treat the symptom for which the compounded drug product was then prescribed, and/or the medical rationale that supports the otherwise premature prescription of a compounded drug product.

99. Nevertheless, the examination reports submitted by the Prescribing Providers to GEICO virtually never contained any explanation as to why the compounded drug product was medically necessary to meet the unique needs of an individual Insured.

100. Moreover, the Prescribing Providers' follow-up examination reports virtually always failed to explain whether the Fraudulent Compounded Pain Cream was effective or whether the patient experienced any side effects. In fact, the follow-up examination reports routinely failed to even reference the fact that a Fraudulent Compounded Pain Cream was prescribed to the patient.

101. The Defendants used the fraudulent prescriptions solicited from the Prescribing Providers and Clinic Controllers to bill GEICO and other insurers hundreds of thousands of dollars for the Fraudulent Compounded Pain Creams.

102. The Defendants, through SMK Pharmacy, typically billed GEICO between $803.09 and $855.26 for a single tube of Fraudulent Compounded Pain Cream.

103. The Defendants submitted these exorbitant charges knowing that the topical efficacy of the Fraudulent Compounded Pain Creams SMK Pharmacy produced and dispensed was unproven, and there are a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost.

104. Defendants knew that there was no legitimate medical need for the Fraudulent Compounded Pain Creams that could explain why a commercially available drug product would

not be appropriate for the patients who were instead prescribed and dispensed the exorbitantly priced Fraudulent Compounded Pain Creams, oftentimes in addition to such commercially available products.

105. The Defendants, solely to maximize profits, caused SMK Pharmacy to specialize in illegal compounding, producing large quantities of compounded drugs in set formulations, as part of the collusive agreements made with the Prescribing Providers and Clinic Controllers to compound and dispense coded, specially marked, formulaic prescriptions.

106. The Fraudulent Compounded Pain Creams produced by SMK Pharmacy: (i) were not medically necessary; (ii) contained combinations of ingredients that produced no significant difference between the compounded drug and comparable, commercially available products; (iii) were almost never prescribed properly under the governing regulations; and (iv) were "prescribed" and produced in large quantities without regard to medical necessity or the regulations governing the appropriate use of compounded drug products – all pursuant to unlawful arrangements among the Defendants, Prescribing Providers, and Clinic Controllers

107. In short, the Fraudulent Compounded Pain Creams produced by SMK Pharmacy and prescribed by the Prescribing Providers working in collusion with SMK Pharmacy served no purpose other than to exploit the Insured's No-Fault benefits so as to financially benefit the Defendants.

1. SMK Pharmacy Specialized in Large Scale Drug Compounding Activity in Violation of New York State and Federal Law Governing Drug Manufacturers and Outsourcing Facilities

108. As stated above, compounded drug products are only appropriate in limited circumstances, should be formulated for an individual patient's needs upon receipt of a valid prescription for an identified individual or a notation on a prescription stating that a compounded

product is necessary for the identified patient. They should not be prescribed and dispensed as a matter of routine therapy. Moreover, compounded drug products should never replace an FDA-approved and commercially available pharmaceutical product that can fulfill the same pharmacological need for the patient.

109. The Pharmacy Defendants, however, blatantly exploited the No-Fault insurance reimbursement system by entering into collusive relationships with the Prescribing Providers and Clinic Controllers involving the marketing and soliciting of prescriptions for the same predetermined Fraudulent Compounded Pain Creams that were dispensed again and again to numerous Insureds involved in minor fender-bender type accidents, generating millions of dollars in fraudulent billing to New York automobile insurers.

110. SMK Pharmacy, acting under the guise of a neighborhood pharmacy, intentionally assembled combinations of expensive drug ingredients solely to produce exorbitantly priced Fraudulent Compounded Pain Creams that it could use to generate huge volumes of inflated billing, as part of collusive, steering relationships with the Prescribing Providers and Clinic Controllers, in which they provided them with kickbacks or other financial incentives in exchange for fraudulent, illusory prescriptions.

111. For example, the Defendants produced, marketed, and dispensed, among others, DCLTM Cream, a predetermined, formulaic Fraudulent Compounded Pain Cream that the Prescribing Providers typically prescribed using a preprinted label or rubber stamp given to them by the Defendants. DCLTM Creams contains:

- Diclofenac 10%
- Cyclobenzaprine 3%
- Lidocaine 5%
- Tetracaine 3%
- Menthol 2%

112. Notably, DCLTM Cream calls for diclofenac sodium in an amount that is more than three times the FDA-approved amount contained in Diclofenac Gel and nearly 7 times the FDA-approved amount contained in Diclofenac Solution.

113. SMK Pharmacy typically billed between $803.09 and $855.26 for a single tube of DCLTM Cream.

114. The combination of drugs used in the Fraudulent Compounded Pain Creams, including DCLTM Cream, was merely a means for the Defendants to inflate the billing and maximize their charges to exploit New York automobile insurance carriers, as pharmacy providers are statutorily reimbursed for each individual ingredient contained in a compounded drug product. As a result, the more constituent drug ingredients SMK Pharmacy includes in its Fraudulent Compounded Pain Creams, the more the Defendants can bill under the name of SMK Pharmacy.

115. Despite the fact that, according to the FDA, traditional pharmacy compounding requires the combining, mixing, or altering of ingredients to create a *customized medication for an individual patient* in response to a licensed practitioner's prescription, the preset prescription labels and rubber stamps – created by the Defendants and distributed to the Prescribing Providers and Clinic Controllers – indicate the Defendants created predetermined compounded drug products and produced them in bulk.

116. By supplying the Prescribing Providers and Clinic Controllers with the preset prescription labels and rubber stamps, the Defendants steered the Prescribing Providers and Clinic Controllers to prescribe, or caused to be prescribed, the Fraudulent Compounded Pain Creams in large volumes and direct those prescriptions to SMK Pharmacy in exchange for kickbacks or other financial incentives.

117. Additionally, the Defendants included both Lidocaine and Tetracaine – two different anesthetics – in every preformulated tube of DCLTM Cream. Not only is it medically unnecessary and clinically nonsensical to include both of these drug ingredients in a topical pain product, but by doing so the Defendants also engaged in duplication of therapy thereby unnecessarily increasing the risk of adverse events to Insureds that purportedly received the DCLTM Fraudulent Compounded Pain Creams.

118. The preformulated Fraudulent Compounded Pain Creams were not created or prescribed by the Prescribing Providers to meet the unique needs of any individual patient.

119. Rather, the Fraudulent Compounded Pain Creams were produced and dispensed by SMK Pharmacy in large quantities without regard to the unique needs of any individual patient.

120. Notably, the Defendants never cited a legitimate medical need for the Fraudulent Compounded Pain Creams that would explain why a commercially available drug product was not appropriate to dispense to the Insureds who received the Fraudulent Compounded Pain Creams.

121. Likewise, the Prescribing Providers never cited a legitimate medical need for the Fraudulent Compounded Pain Creams that would explain why a commercially available drug product was not appropriate to prescribe for the Insureds who received the Fraudulent Compounded Pain Creams. For example, the Prescribing Physicians never indicated the patient had a contraindication to commercially available drug products, and rarely did they document any medication allergies or pre-existing comorbidities that might support the use of Fraudulent Compounded Pain Creams.

122. Accordingly, the Fraudulent Compounded Pain Creams, prescribed by the Prescribing Providers and produced by the Defendants, were never customized for individual

patients. Rather the same Fraudulent Compounded Pain Creams were repeatedly prescribed and dispensed again and again to hundreds of Insureds.

123. SMK Pharmacy and the Fraudulent Compounded Pain Creams are not exempt from FDA oversight and approval, and from similar New York State licensing requirements applicable to drug manufacturers and outsourcing facilities, because the Fraudulent Compounded Pain Creams were illegally compounded in set formulations in large quantities, rather than individualized and tailored to meet specific individual patient needs and provided pursuant to legitimate prescriptions. See 21 U.S.C. § 355 and 21 U.S.C. 353a(a).

124. SMK Pharmacy, by specializing in creating and dispensing large volumes of the Fraudulent Compounded Pain Creams, engaged in bulk compounding activity (akin to that engaged in by drug manufacturers and outsourcing facilities) as opposed to compounding individual prescriptions on a case-by-case basis upon receipt of a valid prescription order.

125. SMK Pharmacy's bulk compounding activity required it to register as a manufacturer or outsourcing facility with the New York State Department of Education, as well as with the FDA, rather than registering as a mere pharmacy.

126. The Defendants' creation and dispensation of predetermined, compounded drug products in large volumes, renders SMK Pharmacy in violation of both state and federal licensing laws regulating the safe manufacturing of drugs.

127. Furthermore, as drug manufacturers and dispensers, the Defendants violated 21 U.S.C. § 355(a) which states that "no person shall introduce or deliver for introduction into interstate commerce any new drug" without first obtaining approval to do so by way of an application filed with the Secretary of Health and Human Services with respect to that drug.

128. A "new drug" – as defined by 21 U.S.C. § 321(p)(1) – is "any drug…the composition of which is such that such drug is not generally recognized…as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof."

129. SMK Pharmacy's Fraudulent Compounded Pain Creams – for which it has billed GEICO hundreds of thousands of dollars – have never been FDA-approved and, therefore, were never verified by the FDA as being safe, effective, or quality products. In fact, SMK Pharmacy's bulk compounding and dispensing of the Fraudulent Compounded Pain Creams exposed Insureds to widespread risks including therapeutic duplication and harmful contraindications, which is why they should only be prescribed under limited and unique circumstances.

2. The Prescription and Dispensation of SMK Pharmacy's Compounded Products is Contrary to Evidenced-Based Medical Practices

130. In keeping with the fact that the Fraudulent Compounded Pain Creams were prescribed pursuant to the Defendants' fraudulent scheme intended to generate profits from insurers, SMK Pharmacy's Fraudulent Compounded Pain Creams (i) have no medical efficacy based on the purported symptoms of the patients receiving the compounded products and (ii) were prescribed without any legitimate reason to provide the patients with expensive compounded products – which include drugs whose efficacy in topical form is undocumented and unsupported – when there are many other widely accepted, proven effective alternatives with well-documented therapeutic benefits commercially available at considerably lower costs.

131. As stated above, the World Health Organization and the Department of Health & Human Services both recommend the use of orally administered non-opioids (e.g., NSAIDs and acetaminophens) as first line therapy for patients for whom medications are clinically appropriate.

132. Because compounded products like the ones dispensed by SMK Pharmacy are not FDA-approved – and therefore not subject to FDA regulations regarding quality, safety, and effectiveness of manufactured drug products – they should never be prescribed as routine therapy.

133. Topical compounded pain creams should be the last prescribed intervention, after oral medications are not tolerated or are deemed ineffective or contraindicated, as well as after any FDA-approved manufactured topical products have been tried but failed to provide sufficient pain relief to the patient.

134. In keeping with the fact that the prescriptions for the Fraudulent Compounded Pain Creams were not prescribed to meet legitimate specific needs of individual patients but rather were prescribed as part of routine therapy, the Insureds in the claims set forth in Exhibit "1" virtually always suffered garden-variety soft tissue injuries such as sprains or strains, to the extent they suffered any injuries at all.

135. Ordinary soft tissue injuries such as sprains or strains almost always resolve after a short course of conservative treatment, or no treatment at all. It is highly improbable that a compounded drug product would be necessary to treat a soft tissue injury several months after an Insureds' car accident.

136. It is even more improbable – to the point of impossibility – that a compounded drug product would be necessary to treat a soft tissue injury several months after an Insured's car accident for a substantial majority of Insureds who purportedly received treatment from the Prescribing Providers at the No-Fault Clinics.

137. However, numerous Insureds who had soft tissue injuries resulting from minor automobile accidents and treated with Prescribing Providers at No-Fault Clinics received

prescriptions for Fraudulent Compounded Pain Creams several months after their automobile accidents.

138. Moreover, even in the rare event that an Insured receiving treatment from one of the Prescribing Providers at the No-Fault Clinics continued to experience significant pain months after that Insured's alleged automobile accident, there is no evidence supporting the prescription of the Fraudulent Compounded Pain Creams to resolve that pain.

139. For a topical formulation to be effective, it must be able to penetrate the skin so that it can reach the nerve or tissue receptors responsible for producing or transmitting a person's sensation of pain.

140. The skin is composed of three layers: epidermis, dermis, and hypodermis. Within the epidermis, the stratus corneum is the outermost layer of the skin that serves as the main barrier to drug entry. For analgesic medicines to be absorbed through the skin, they must contain optimal drug combinations, effective concentrations of each drug, and a compounding base with the appropriate physiochemical properties to facilitate absorption. In general, creams are less effective than gels or sprays in penetrating the skin.

141. In almost all scenarios, oral pain relievers are superior to all topical formulations because they reduce or alleviate pain by entering the bloodstream through the gastrointestinal system making travel to the relevant nerve or tissue receptors easy.

142. Some of the limited circumstances in which a physician should prescribe a topical medication instead of oral pain relievers include for patients in whom these oral medications are contraindicated such as those with moderate to severe kidney or liver dysfunction, or those with comorbidities that preclude the use of oral NSAIDs (e.g., history of peptic ulcer disease, coronary artery disease, or congestive heart failure).

143. SMK Pharmacy's Fraudulent Compounded Pain Creams contain combinations of drugs which have no medical evidentiary support and no efficacious value in treating musculoskeletal and neuropathic injuries – even assuming the Insureds treated by the Prescribing Providers actually suffered from such injuries.

144. There are no published, peer-reviewed, controlled studies to support that patients who suffer from musculoskeletal pain or neuropathy have achieved any therapeutic effect from using topical pain creams containing the drugs that are part of the Fraudulent Compounded Pain Creams.

145. Further, many of the Fraudulent Compounded Pain Creams are available in alternative oral formulations or are commercially available in different topical formulations at a fraction of the cost.

146. The alternatives to the Fraudulent Compounded Pain Creams, whether in oral formulations or commercially available topical formulations at fraction of the cost, are FDA-approved and commonly prescribed by healthcare providers who utilize evidence-based medicine for their prescribing practices.

147. Contrary to evidenced-based medical practices, in exchange for kickbacks or other financial incentives, the Prescribing Providers routinely prescribed the Fraudulent Compounded Pain Creams without regard to whether other forms of oral and/or topical medications approved for the treatment of pain failed, or whether there was a contraindication for their use.

148. The Prescribing Providers failed to practice evidence-based medicine. Rather, the Prescribing Providers prescribed the Fraudulent Compounded Pain Creams based on their illegal, collusive arrangements with the Defendants who employed a fraudulent, predetermined treatment and billing protocol designed to financially exploit Insureds by causing the Prescribing Providers

and Clinic Controllers to steer prescriptions for the Fraudulent Compounded Pain Creams to SMK Pharmacy in exchange for kickbacks or other financial incentives.

149. As a result of these collusive arrangements, the Defendants frequently purported to dispense preformulated Fraudulent Compounded Pain Creams pursuant to prescriptions from the Prescribing Providers that were not individualized or tailored to meet the patient's specific individual needs. These prescriptions were often issued upon initial examination, without indication that any other forms of oral or topical medications failed or were contraindicated, and at times, despite the presence of significant factors in the Insureds' medical histories. For example:

(i) Insured JB was involved in a minor motor vehicle accident on April 16, 2018. She sought treatment at a No-Fault Clinic located at 1575 East 19th Street, Brooklyn, New York and on April 19, 2018 underwent an initial examination with David Lifschutz, M.D. ("Dr. Lifschutz") of Integrated Neurological Associates, PLLC ("Integrated Neuro"). At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On April 23, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated April 19, 2018. Notably, on April 19, 2018 Dr. Lifschutz also prescribed an oral NSAID and an oral muscle relaxer (i.e., celecoxib and tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained both an NSAID and muscle relaxer. The Defendants dispensed the celecoxib, tizanidine and DCLTM Cream simultaneously on April 23, 2018.

(ii) Insured CL was involved in a minor motor vehicle accident on March 30, 2019. He sought treatment at a No-Fault Clinic located at 1926 Victory Boulevard, Staten Island, New York and on April 10, 2019 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On April 18, 2019, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated April 17, 2019. Notably, on April 17, 2019 Dr. Lifschutz also prescribed an oral muscle relaxer (i.e., tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained a muscle relaxer. The

Defendants dispensed the tizanidine and DCLTM Cream simultaneously on April 18, 2019.

(iii) Insured FT was involved in a minor motor vehicle accident on May 26, 2019. He sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on June 4, 2019 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On June 5, 2019, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated June 4, 2019.

(iv) Insured JW was involved in a minor motor vehicle accident on February 1, 2018. She sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on February 27, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On February 28, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated February 27, 2018. Notably, on February 27, 2018 Dr. Lifschutz also prescribed an oral NSAID and an oral muscle relaxer (i.e., celecoxib and tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained both an NSAID and muscle relaxer. The Defendants dispensed the celecoxib, tizanidine and DCLTM Cream simultaneously on February 28, 2018.

(v) Insured EA was involved in a minor motor vehicle accident on June 7, 2018. She sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on June 19, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On July 2, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated June 19, 2018. Defendants dispensed additional DCLTM Cream to the Insured on November 9, 2018 but did not submit any prescriptions in support of their claim for reimbursement. The Defendants dispensed another DCLTM Cream to the Insured on July 8, 2019 pursuant to a prescription by Dr.

Lifschutz dated July 1, 2019.

(vi) Insured HD was involved in a minor motor vehicle accident on November 15, 2018. He sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on November 27, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On November 28, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured. The Defendants did not submit any prescriptions in support of their claim for reimbursement.

(vii) Insured JC was involved in a minor motor vehicle accident on December 2, 2018. She sought treatment at a No-Fault Clinic located at 1926 Victory Blvd, Staten Island, New York and on December 5, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On December 6, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream. Notably, Dr. Lifschutz also prescribed an oral muscle relaxer (i.e., tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained a muscle relaxer. The Defendants dispensed the tizanidine and DCLTM Cream simultaneously on December 6, 2018. The Defendants did not submit any prescriptions in support of their claim for reimbursement. Furthermore, the Insured has a history of hypertension. Patients with hypertension are at a greater risk of cardiovascular events potentially caused by NSAIDs such as the diclofenac in DCLTM Cream. Despite these risks, the Defendants dispensed celecoxib, an oral NSAID, on January 9, 2019 and February 28, 2019 pursuant to prescriptions by Dr. Lifschutz dated January 9, 2019 and February 27, 2019, respectively.

(viii) Insured BL was involved in a minor motor vehicle accident on April 11, 2019. He sought treatment at a No-Fault Clinic located at 1926 Victory Blvd, Staten Island, New York and on May 1, 2019 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On May 2, 2019, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by

Dr. Lifschutz dated May 1, 2019. Notably, Dr. Lifschutz also prescribed an oral muscle relaxer (i.e., tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained a muscle relaxer. The Defendants dispensed the tizanidine and DCLTM Cream simultaneously on May 2, 2019.

(ix) Insured LF was involved in a minor motor vehicle accident on October 11, 2018. She sought treatment at a No-Fault Clinic located at She sought treatment at a No-Fault Clinic located 1926 Victory Boulevard, Staten Island, New York and on October 24, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On November 15, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured. Notably, Dr. Lifschutz also prescribed an oral NSAID and an oral muscle relaxer (i.e., naproxen and cyclobenzaprine) resulting in therapeutic duplication since the DCLTM Cream already contained both an NSAID and cyclobenzaprine. The Defendants dispensed the naproxen on October 25, 2018 and the cyclobenzaprine and DCLTM Cream simultaneously on November 15, 2018. The Defendants did not submit any prescriptions in support of their claims for reimbursement. The Defendants dispensed additional DCLTM Cream to the Insured on January 2, 2019 and meloxicam, another oral NSAID, on January 24, 2019, pursuant to prescriptions by Dr Lifschutz dated January 2, 2019 and January 23, 2019, respectively.

(x) Insured DB was involved in a minor motor vehicle accident on April 10, 2018. She sought treatment at a No-Fault Clinic located 277 Burnside Avenue, Lawrence, New York and on April 24, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On April 30, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated April 24, 2018. Defendants dispensed another DCLTM Cream to the Insured on August 20, 2018 but did not submit any prescriptions in support of their claim for reimbursement.

(xi) Insured KP was involved in a minor motor vehicle accident May 24, 2019. She sought treatment at a No-Fault Clinic located 1575 East 19th Street, Brooklyn, New York and on June 6, 2019 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications failed or were contraindicated.

Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On June 10, 2019, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated June 6, 2019. Defendants dispensed another DCLTM Cream to the Insured on January 17, 2020 pursuant to a prescription by Dr. Lifschutz dated January 16, 2020.

(xii) Insured RM was involved in a minor motor vehicle accident on April 25, 2018. He sought treatment at a No-Fault Clinic located at 1575 East 19th Street, Brooklyn, New York and on May 9, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications were tried or contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On May 11, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifshutz dated May 9, 2018. Notably, Dr. Lifschutz also prescribed an oral NSAID and an oral muscle relaxer (i.e., celecoxib and tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained both an NSAID and muscle relaxer. The Defendants dispensed the celecoxib, tizanidine, and DCLTM Cream simultaneously on May 11, 2018. The Defendants dispensed additional DCLTM Cream to the Insured on June 29, 2018 but the Defendants did not submit a prescription in support of their claim for reimbursement. Notably, the Insured had a history of hypertension. Patients with hypertension and coronary artery disease are at a greater risk of cardiovascular events potentially caused by NSAIDs such as the diclofenac in DCLTM Cream.

(xiii) Insured MM was involved in a minor motor vehicle accident on January 9, 2018. She sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on February 27, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications were tried or contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On March 2, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated February 27, 2018. Notably, on February 27, 2018 Dr. Lifschutz also prescribed an oral NSAID and an oral muscle relaxer (i.e., celecoxib and tizanidine) resulting in therapeutic duplication since the DCLTM Cream already contained both an NSAID and muscle relaxer. The Defendants dispensed the celecoxib, tizanidine and DCLTM Cream simultaneously on March 2, 2018 and again on May 11, 2018, and additional DCLTM Cream on June 29, 2018.

(xiv) Insured VD was involved in a minor motor vehicle accident on February 3, 2018. He sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on March 20, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications were tried or contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On March 27, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated March 20, 2018.

(xv) Insured RC was involved in the same minor motor vehicle accident as Insured V.D., supra, on February 3, 2018. He sought treatment at a No-Fault Clinic located at 277 Burnside Avenue, Lawrence, New York and on March 20, 2018 underwent an initial examination with Dr. Lifschutz of Integrated Neuro. At the time of the initial examination, Dr. Lifschutz did not indicate the Insured had a legitimate need for a compounded medication or that any other forms of oral or topical medications were tried or contraindicated. Nevertheless, the Insured was prescribed a preformulated Fraudulent Compounded Pain Cream, DCLTM Cream, that was not individualized or tailored to the Insured's specific needs. On March 27, 2018, the Defendants purported to dispense the Fraudulent Compounded Pain Cream to the Insured pursuant to a prescription by Dr. Lifschutz dated March 20, 2018.

150. These are only representative examples. In the claims for Fraudulent Compounded Pain Creams that are identified in Exhibit "1", the Defendants frequently dispensed preformulated Fraudulent Compounded Pain Creams, primarily in the form of DCLTM Cream, that were not individually tailored to the specific needs of the Insureds who purportedly received them.

151. When prescribing the Fraudulent Compound Pain Cream, the Prescribing Providers did not document in their examination reports whether the patients were intolerant of commercially available products (oral or topical), or whether any commercially available products (oral or topical) were recommended to the patient.

152. The Prescribing Providers also failed to document in their examination reports any contraindication to oral NSAIDs or why a compounded topical drug product was medically necessary or appropriate for a specific patient. They also failed to document why the particular

Fraudulent Compounded Pain Cream – often DCLTM Cream – was medically necessary for a specific patient.

153. The Prescribing Providers also failed to document in their follow-up examination reports: (i) whether the Fraudulent Compounded Pain Cream prescribed to a particular patient was used by the patient; or (ii) whether the Fraudulent Compounded Pain Cream provided any pain relief to the patient or was otherwise effective for the purpose prescribed.

154. The Prescribing Providers plainly and continuously failed to prescribe individually tailored compounded products, made for identified individual Insureds, and capable of producing a significantly better result than a comparable, commercially available product.

155. Likewise, SMK Pharmacy plainly and continuously failed to dispense individually tailored compounded products, made for identified individual Insureds, and capable of producing a significantly better result than a comparable, commercially available product.

156. The Prescribing Providers and Clinic Controllers wrote, or caused to be written, the prescriptions for the Fraudulent Compounded Pain Cream and the Defendants filled those prescriptions pursuant to the illegal, collusive arrangements among the Defendants, Prescribing Providers, and Clinic Controllers designed to maximize profits.

157. To-date, the Defendants, through SMK Pharmacy, have submitted over $819,500.00 in claims seeking reimbursement for Fraudulent Compounded Pain Creams.

D. The Fraudulent Charges for Diclofenac Gels and Diclofenac Solutions

158. As a further part of the fraudulent scheme, Defendants routinely billed GEICO for exorbitantly priced topical diclofenac sodium, primarily in the form of diclofenac sodium 1.5% solution (i.e., "Diclofenac Solution"), pursuant to prescriptions purportedly authorized by various

Prescribing Providers operating from numerous No-Fault Clinics. Also pursuant to the fraudulent scheme, Defendants routinely billed for diclofenac sodium 3% gel (i.e., Diclofenac Gel).

159. The Defendants solicited the Prescribing Providers and Clinic Controllers to provide them with voluminous prescriptions for Diclofenac Solution and Diclofenac Gel (together, "Topical Diclofenac") because the Defendants could readily buy Topical Diclofenac at low cost and then have SMK Pharmacy bill GEICO and other New York No-Fault insurers huge sums.

160. Diclofenac Solutions in 1 to 1.5% concentrations are topical NSAIDs typically used to treat joint pain caused by osteoarthritis in the hands, wrists, elbows, knees, ankles, or feet. It has not been proven safe or effective for treating strains or sprains.

161. Diclofenac Gel in 3% concentration is typically used to treat a skin condition known as actinic keratoses.

162. The Prescribing Providers routinely prescribed and the Defendants routinely dispensed Diclofenac Solution despite the fact that virtually none of the Insureds suffered from osteoarthritis.

163. The Prescribing Providers routinely prescribed and the Defendants routinely dispensed Diclofenac Gel despite the fact that none of the Insureds suffered from actinic keratoses.

164. Topical Diclofenac does not have any proven efficacy or safety in the treatment of musculoskeletal injuries, nor is the use of Diclofenac Gel or Diclofenac Solution to treat musculoskeletal injuries an accepted off-label use.

165. The United States Food and Drug Administration ("FDA") requires that all diclofenac sodium prescriptions contain a "Black Box Warning" indicating the potential for serious cardiovascular and gastrointestinal risks.

166. A "Black Box Warning" is the strictest warning attached to the labeling of a prescription drug or product by the FDA and is designed to call attention to serious or life-threatening risks associated with the drug or product.

167. Specifically, with every diclofenac sodium prescription, the FDA requires the patient be warned that: (i) diclofenac sodium may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal; and (ii) diclofenac sodium may cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

168. Notwithstanding the proper and common uses for Topical Diclofenac, or the risks associated with diclofenac sodium in topical form, the Defendants steered the Prescribing Providers to prescribe diclofenac sodium in the form of Topical Diclofenac while oftentimes recommending the patient continue the use of oral NSAIDs, such as ibuprofen, naproxen, celecoxib, and meloxicam, or simultaneously prescribing oral NSAIDs.

169. Not only were the prescriptions for both the topical and the oral NSAIDs issued simultaneously, but oftentimes both prescriptions allowed for multiple refills.

170. Moreover, at times, more than one Prescribing Provider issued simultaneous prescriptions for both a topical and an oral NSAID to a single Insured.

171. Prescribing Diclofenac Gel or Diclofenac Solution, while simultaneously prescribing and dispensing oral NSAIDS to patients, is therapeutic duplication which results in increased risk of adverse events with no additional therapeutic benefit.

172. Nevertheless, the Prescribing Providers consciously prescribed Diclofenac Gels or Solutions in conjunction with oral NSAIDs and/or other Fraudulent Topical Pain Products to numerous Insureds, despite the risks it posed to the Insureds' health and well-being.

173. The Defendants then simultaneously dispensed the Topical Diclofenac and the oral NSAIDS to Insureds on the exact same date, without counseling the Insureds on the risks or dangers associated with the concurrent use of Topical Diclofenac and oral NSAIDs. For example:

(i) Insured EF was involved in a minor motor vehicle accident on December 3, 2018. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Joyce Goldenberg, M.D. ("Dr. Goldenberg") and Donna Carlin, P.A. ("PA Carlin") of Central Park Physical Medicine and Rehabilitation, P.C. ("Central Park PC"). On December 22, 2018, the Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Solution and naproxen) along with 90 Lidocaine Patches and cyclobenzaprine pursuant to prescriptions issued by PA Carlin on December 19, 2018. Each of the prescriptions allowed for two refills. The Defendants dispensed refills of these Fraudulent Pharmaceuticals to the Insured on January 22, 2019 and May 14, 2019. E.F. suffered from grade 2 hypertension and presented at the time of his examination with blood pressure of 150/100. This medical history is a high-risk contraindication to the Insured's use of NSAIDs such as Diclofenac Solution and naproxen.

(ii) Insured NS was involved in a minor motor vehicle on April 3, 2019. He sought treatment at a No-Fault Clinic located at 125-10 Queens Boulevard, Kew Gardens, New York where he came under the care of Siddhartha Sharma, DPM ("Dr. Sharma") of McCulloch Orthopaedic Surgical Services PLLC ("McCulloch Ortho"). On April 26, 2019, the Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Gel and naproxen) as well as baclofen pursuant to prescriptions issued by Dr. Sharma on April 9, 2019. The treatment plan of Dr. Sharma's initial examination report only called for prescriptions for naproxen and baclofen and made no mention of a prescription for Diclofenac Gel.

(iii) Insured KRR was involved in a minor motor vehicle accident on July 20, 2019. She sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and Tara LaRocca, P.A. Carlin, P.A. ("PA LaRocca") of Central Park PC. On August 13, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., diclofenac 1% gel and naproxen) along with 60 Lidocaine Patches, Fiorinal (butalbital, aspirin, and caffeine), and baclofen pursuant to prescriptions issued by PA LaRocca on August 12, 2019. The prescriptions for diclofenac 1% gel, naproxen, Lidocaine Patches, and baclofen each allowed for two refills. On October 11, 2019, the Defendants dispensed to the Insured celecoxib (another oral NSAID), oxycodone, docusate, and ondansetron pursuant to prescriptions issued by Steven Struhl, M.D. ("Dr. Struhl") on October 10, 2019. The prescription for celecoxib allowed for three refills. The Defendants dispensed refills of the diclofenac 1% gel, celecoxib, baclofen, and Lidocaine Patches on November 13, 2019 and December 14, 2019 pursuant to the prescriptions issued by PA LaRocca and Dr. Struhl. On

February 29, 2020, Defendants dispensed another refill of celecoxib along with an additional 60 Lidocaine Patches pursuant to a new prescription issued by Ari Lerner, M.D. ("Dr. Lerner") on February 26, 2020 and which allowed for one refill. On May 6, 2020, Defendants dispensed to the Insured 90 Lidocaine Patches and Tylenol pursuant new prescriptions issued by Dr. Goldenberg on April 28, 2020. These prescriptions each allowed for two refills. The prescription of Fiorinal is no longer within best practice guidelines due to increased risks of gastrointestinal bleeding and its addictive properties due to high caffeine levels. Furthermore, Fiorinal contains aspirin, yet another NSAID, exposing the Insured to therapeutic triplication.

(iv) Insured EC was involved in a minor motor vehicle accident on July 6, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg, PA LaRocca, and PA Carlin of Central Park PC. On August 8, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Solution and naproxen) along with 60 Lidocaine Patches pursuant to prescriptions issued by PA LaRocca on July 29, 2019. Each of these prescriptions allowed for two refills. The Defendants dispensed refills of each Fraudulent Pharmaceutical to the Insured on September 12, 2019. On October 17, 2019, Defendants dispensed a refill of naproxen, and dispensed 90 Lidocaine Patches and Diclofenac Solution pursuant to prescriptions issued by PA Carlin on September 11, 2019. At the time PA Carlin issued these prescriptions, there were two remaining refills on the prescriptions issued by PA LaRocca on July 29, 2019. On December 30, 2019, Defendants dispensed to the Insured celecoxib (another oral NSAID), Endocet (oxycodone), ondansetron, and docusate pursuant to prescriptions issued by Dr. Struhl on December 26, 2019. Finally, on January 21, 2020, Defendants dispensed refills of Lidocaine Patches and Diclofenac Solution pursuant to the prescriptions issued by PA Carlin.

(v) Insured JR was involved in a minor motor vehicle accident on October 11, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg and PA LaRocca of Central Park PC. On October 19, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., diclofenac 1% gel and naproxen) along with 60 Lidocaine Patches, baclofen, and Fiorinal (butalbital, aspirin, and caffeine) pursuant to prescriptions issued by PA LaRocca on October 17, 2019. The prescriptions for diclofenac 1% gel, naproxen, Lidocaine Patches, and baclofen each allowed for two refills. The Defendants dispensed refills of each of these Fraudulent Pharmaceuticals to the Insured on December 20, 2019 and February 13, 2020. Additionally, on October 12, 2019, Rite Aid Pharmacy dispensed ibuprofen to the Insured pursuant to a prescription by Spencer Douglas, M.D. The prescription of Fiorinal is no longer within best practice guidelines due to increased risks of gastrointestinal bleeding and its addictive properties due to high caffeine levels. Furthermore, Fiorinal contains aspirin, yet another NSAID, exposing the Insured to therapeutic triplication.

(vi) Insured AKT was involved in a minor motor vehicle accident on October 8, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg and PA LaRocca of Central Park PC. On October 31, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., diclofenac 1% gel and naproxen) along with 60 Lidocaine Patches, baclofen, and Fiorinal (butalbital, aspirin, and caffeine) pursuant to prescriptions issued by PA LaRocca on October 29, 2019. The prescriptions for diclofenac 1% gel, naproxen, and Lidocaine Patches each allowed for two refills and the prescription for baclofen allowed for one refill. The Defendants dispensed refills of each of these Fraudulent Pharmaceuticals to the Insured on December 14, 2019. The prescription of Fiorinal is no longer within best practice guidelines due to increased risks of gastrointestinal bleeding and its addictive properties due to high caffeine levels. Furthermore, Fiorinal contains aspirin, yet another NSAID, exposing the Insured to therapeutic triplication.

(vii) Insured AA was involved in a minor motor vehicle accident on April 30, 2019. She sought treatment at a No-Fault Clinic located at 200 Madison Avenue, New York, New York where he came under the care of Dr. Goldenberg, PA LaRocca, and Lin Shen, P.A. ("PA Shen") of Central Park PC. On May 11, 2019, Defendants dispensed to the Insured an oral NSAID (naproxen) along with 90 Lidocaine Patches, and cyclobenzaprine pursuant to prescriptions issued by PA Carlin on May 6, 2019. The prescriptions for naproxen and Lidocaine Patches each allowed for two refills. On August 2, 2019, Defendants dispensed the refills of naproxen and Lidocaine Patches pursuant to the prescriptions issued by PA Carlin, along with diclofenac 1% gel pursuant to a prescription by PA Shen issued on July 29, 2019 and which allowed for two refills. In addition to the Fraudulent Pharmaceuticals dispensed by Defendants, True Health Pharmacy Inc. dispensed naproxen and oxycodone to the Insured on June 7, 2019 and naproxen again on June 24, 2019 pursuant to prescriptions issued by Mark McMahon, M.D.

(viii) Insured WM was involved in a minor motor vehicle accident on October 13, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On November 1, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Solution and naproxen) along with 60 Lidocaine Patches pursuant to prescriptions issued by PA Carlin on October 29, 2019. The prescriptions for each Fraudulent Pharmaceutical allowed for two refills.

(ix) Insured KG was involved in a minor motor vehicle accident on September 9, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On September 28, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Solution and naproxen) along with 90 Lidocaine Patches and cyclobenzaprine pursuant to prescriptions issued by PA Carlin on September 25, 2019. The prescriptions for Diclofenac Solution, naproxen, and Lidocaine Patches each allowed for two refills. The Defendants

dispensed refills of these Fraudulent Pharmaceuticals on November 9, 2019 and December 11, 2019. In addition to dispensing the Fraudulent Pharmaceuticals, on February 1, 2020 the Defendants dispensed oxycodone to the Insured pursuant to a prescription issued by Dr. Struhl on January 31, 2020.

(x) Insured VS was involved in a minor motor vehicle accident on August 16, 2019. She sought treatment at a No-Fault Clinic located at 200 Madison Avenue, New York, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On October 16, 2019, Defendants dispensed to the Insured both a topical and an oral NSAID (i.e., Diclofenac Solution and naproxen) along with 60 Lidocaine Patches pursuant to prescriptions issued by PA Carlin on October 2, 2019. The prescriptions for each Fraudulent Pharmaceutical allowed for two refills. Defendants dispensed refills of each Fraudulent Pharmaceutical to the Insured on November 16, 2019 and December 27, 2019.

174. In the instant matter, by engaging in such therapeutic duplication – and, at times, therapeutic triplication – the Prescribing Providers and the Defendants put patients at increased risk of cardiovascular and gastrointestinal events (without any additional therapeutic benefit) as the use of oral NSAIDs increases the "Black Box Warning" risks associated with diclofenac sodium.

175. The Diclofenac Gels and Diclofenac Solutions were prescribed pursuant to collusive arrangements and predetermined treatment protocols, and without regard for patient care and safety, or the commercial availability of a wide range of FDA-approved medications, as well as over-the-counter medications, proven to have therapeutic effects and available at a fraction of the cost.

176. In keeping with the fact that Diclofenac Gels and Diclofenac Solutions were prescribed and dispensed pursuant to predetermined treatment protocols and without regard for patient care and safety, the initial examination reports prepared by the Prescribing Providers virtually never stated the medical basis for the prescriptions and, in some cases, failed to acknowledge that the patient was even being prescribed Topical Diclofenac.

177. In further keeping with the fact that the Diclofenac Gels and Diclofenac Solutions were prescribed and dispensed pursuant to predetermined treatment protocols and without regard for patient care, the follow-up examination reports performed by the Prescribing Providers virtually never addressed whether the Diclofenac Gels and Diclofenac Solutions prescribed provided any pain relief to the patient or was otherwise effective for the purpose prescribed, to what degree, or whether the patients experienced any side effects.

178. SMK Pharmacy typically billed GEICO between $909.89 and $948.59 for a single tube of Diclofenac Gel.

179. SMK Pharmacy typically billed GEICO between $212.59 and $1,108.69 for a single bottle of Diclofenac Solution.

180. To-date, the Defendants, through SMK Pharmacy, have submitted over $682,089.00 in claims seeking reimbursement for Topical Diclofenac.

181. Not surprisingly, the Office of Inspector General of the U.S. Department of Health & Human Services issued a report which noted that one of the most common products billed for by pharmacies with questionable billing was diclofenac sodium because, among other reasons, there is a striking difference between the cost of a compounded topical containing diclofenac sodium and a non-compounded version of the same drug. In that same report, the OIG also noted that many pharmacies in New York State are among the most questionable in the nation. See Questionable Billing For Compounded Topical Drugs in Medicare Part D, OEI-02-16-00440 (August 2018).

E. The Fraudulent Charges for Lidocaine 5% Ointment and Patches

182. In addition to the egregious amount of Diclofenac Gel and Diclofenac Solution dispensed by the Defendants to Insureds, in accordance with the fraudulent scheme discussed

above, the Defendants also submitted exorbitant claims for various other Fraudulent Topical Pain Products, including Lidocaine 5% Ointment and Lidocaine Patches (collectively the "Lidocaine Products").

183. Lidocaine 5% Ointment is primarily indicated for temporary pain relief associated with minor burns and skin irritations such as sunburn, insect bites, poison ivy, poison oak, poison sumac, abrasions of the skin and insect bites, or as a topical anesthetic for minor procedures such as sutures or injections.

184. Lidocaine is a local anesthetic (numbing medication) that works by blocking nerve signals in the top few millimeters of skin. Lidocaine does not penetrate the skin enough to treat deep musculoskeletal pain, nor is it indicated for this type of condition.

185. Excessive dosage or short intervals between doses of Lidocaine 5% Ointment can cause adverse effects including, among others, bradycardia, hypotension, and cardiovascular collapse that may lead to cardiac arrest. Accordingly, patients should be instructed to strictly adhere to the recommended dosage and a single application of Lidocaine 5% Ointment should not exceed 5 grams.

186. Despite this, the Prescribing Providers never recommended Insureds first use over-the-counter lidocaine products to treat their minor aches and pains sustained in fender-bender type motor vehicle accidents. Rather, pursuant to collusive arrangements and predetermined protocols, the Prescribing Providers routinely prescribed Insureds Lidocaine 5% Ointment and, along with the Clinic Controllers, directed the prescriptions to SMK Pharmacy.

187. For example, the Prescribing Providers never recommended Insureds first try commonly available commercial products, such as Icy Hot Lidocaine or Aspercreme with Lidocaine, both of which contain 4% lidocaine and are available at most well-known pharmacy

retailers at a mere fraction of the cost, including Rite-Aid and Target for advertised prices in the range of approximately $10.00 or less.

188. As with the prescriptions for Topical Diclofenac, the initial examination reports prepared by the Prescribing Providers virtually never set forth the medical basis for the Lidocaine 5% Ointment prescriptions and, in some cases, failed to acknowledge that the patient was even being prescribed a Lidocaine 5% Ointment. Likewise, the follow-up examination reports virtually never addressed whether the Lidocaine 5% Ointment prescribed provided any pain relief to the patient or was otherwise effective for the purpose prescribed, to what degree, or whether the patients experienced any side effects.

189. As a further part of the scheme, SMK Pharmacy also frequently billed GEICO for exorbitantly-priced pain patches – primarily in the form of lidocaine 5% patches (i.e., Lidocaine Patches), pursuant to duplicitous prescriptions solicited from the Prescribing Providers and the Clinic Controllers in exchange for kickbacks or other incentives.

190. In keeping with the fact that the Defendants caused the Prescribing Providers and Clinic Controllers to prescribe the Fraudulent Topical Pain Products and steer those prescriptions to the SMK Pharmacy pursuant to predetermined protocols designed to maximize profits without regard for patient care, the Lidocaine Patches were routinely dispensed and billed at exorbitant prices despite the availability of less expensive, commercially available FDA-approved patches.

191. Notably, Lidocaine Patches are primarily used to treat chronic post-herpetic neuropathic pain, although studies have shown that any relief these patches provide – beyond topical anesthetic relief – is more attributable to its placebo effect rather than the pharmacological action of the Lidocaine Patches themselves. In fact, Lidocaine Patches are insufficient to produce a complete sensory block.

192. Nevertheless, the Prescribing Providers routinely prescribed these patches to Insureds for sprain/strain injuries sustained in fender-bender type motor vehicle accidents.

193. The Lidocaine Patches were routinely prescribed at the time of the initial examination – during the acute stages of the Insureds' pain symptoms.

194. Like the prescriptions for Lidocaine 5% Ointment, the Prescribing Providers never recommended Insureds first use over-the-counter lidocaine products – which are available to treat their often acute, minor strain/sprain injuries. Rather, the Prescribing Providers routinely prescribed Insureds Lidocaine Patches.

195. As with the prescriptions for the other Fraudulent Topical Pain Products, the initial examination reports prepared by the Prescribing Providers virtually never set forth the medical basis for the prescriptions and, in some cases, failed to acknowledge that the patient was even being prescribed Lidocaine Patches. Likewise, the follow-up examination reports virtually never addressed whether the Lidocaine Patches prescribed provided any pain relief to the patient or were otherwise effective for the purpose prescribed, to what degree, or whether the patients experienced any side effects.

196. In keeping with the fact that the Defendants acted with gross indifference to patient care and safety, the patients were generally not instructed on the safe use, side effects or risks associated with the Lidocaine Patches.

197. Moreover, the Prescribing Providers regularly prescribed Lidocaine Patches while also prescribing or recommending the patients use heating pads. The use of heating pads is a contraindication to the use of Lidocaine Patches. Specifically, Lidocaine Patches release medication slowly over the course of 12 hours. Lidocaine Patches are not to be applied for longer than 12 hours and should only be applied once in a 24-hour period to avoid toxicity levels. The

use of heating pads accelerates the release of the medication causing the full amount of active ingredients in the patch to release all at once in a short time increasing the risks of toxicity.

198. In keeping with the fact that the Defendants submitted bills pursuant to collusive arrangements with the Prescribing Providers and Clinic Controllers and pursuant to fraudulent, predetermined and profit-driven treatment protocols, the Lidocaine 5% Ointment and Lidocaine Patch prescriptions, like the Topical Diclofenac prescriptions, were often issued contemporaneous to oral NSAIDs and muscle relaxers as well as other Fraudulent Topical Pain Products. For example:

(i) Insured DB was involved in a minor motor vehicle accident on September 10, 2019. She sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and PA LaRocca of Central Park PC. On September 14, 2019, the Defendants dispensed to the Insured 60 Lidocaine Patches, Diclofenac Solution, baclofen, and naproxen pursuant to prescriptions issued by PA LaRocca on September 12, 2019 – two days post-accident. Each of the prescriptions allowed for two refills except the prescription for baclofen which allowed for one refill. The Defendants dispensed the Lidocaine Patch and naproxen refills to the Insured on November 6, 2019. This patient was also prescribed a heating pad.

(ii) Insured JV was involved in a minor motor vehicle accident on August 4, 2019. He sought treatment at a No-Fault Clinic located at 2 West 86th Street, Yonkers, New York where he came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On August 21, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, cyclobenzaprine, methylprednisolone, and Tylenol pursuant to prescriptions issued by PA Carlin on August 9, 2019 – five days post-accident. The prescriptions for Tylenol, Lidocaine Patches and Diclofenac Solution each allowed for two refills. The Defendants dispensed the Lidocaine Patch and Diclofenac Solution refills on November 7, 2019 and January 3, 2020. The Insured has a history of hypertension and cardiac autoantibodies placing him at a greater risk of cardiovascular events potentially caused by NSAIDs such as Diclofenac Solution. He also has a history of atrial fibrillation which is a contraindication to the use of lidocaine as a risk of lidocaine is cardia arrythmia. This risk was accelerated by the fact that the patient was also prescribed a heat pad which was dispensed by Defendants on August 21, 2019.

(iii) Insured FB was involved in a minor motor vehicle accident on September 27, 2019. She sought treatment at a No-Fault Clinic located at 200 Madison Avenue, New York, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On October 4, 2019, the Defendants dispensed to the Insured 90 Lidocaine

Patches, Diclofenac Solution, cyclobenzaprine, and naproxen pursuant to prescriptions issued by PA Carlin on October 2, 2019 – five days post-accident. The prescriptions for naproxen, Lidocaine Patches and Diclofenac Solution each allowed for two refills. The patient was also prescribed a heat pad which was dispensed by Defendants on October 4, 2019.

(iv) Insured KS was involved in a minor motor vehicle accident on September 19, 2019. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where he came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On September 26, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, cyclobenzaprine, and naproxen pursuant to prescriptions issued by PA Carlin on September 25, 2019 – six days post-accident. The prescriptions for naproxen, Lidocaine Patches and Diclofenac Solution each allowed for two refills. The Defendants dispensed the refills of naproxen, Lidocaine Patches, and Diclofenac Solution to the Insured on November 16, 2019 and December 13, 2019. The patient was also prescribed a heat pad which was dispensed by Defendants on September 26, 2019.

(v) Insured KC was involved in a minor motor vehicle accident on August 3, 2018. He sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and PA LaRocca of Central Park PC. On August 14, 2018, the Defendants dispensed to the Insured 60 Lidocaine Patches, Diclofenac Solution, cyclobenzaprine, and naproxen pursuant to prescriptions issued by PA LaRocca on August 13, 2018 – ten days post-accident. Each of the prescriptions allowed for two refills. On August 25, 2018, the Defendants dispensed additional oral NSAIDs and muscle relaxers (i.e., meloxicam and tizanidine) to the Insured pursuant to prescriptions issued by PA LaRocca on August 22, 2018 and which allowed for one refill for each pharmaceutical. The Defendants dispensed the refills of all five medications to the Insured on September 28, 2018. On November 5, 2018, the Defendants dispensed oxycodone, ondansetron, celecoxib (another NSAID), and docusate pursuant to prescriptions issued by Richard Seldes, M.D. ("Dr. Seldes"). On December 4, 2018, the Defendant dispensed the additional refills of Lidocaine Patches and Diclofenac Solution. Also on December 4, 2018, the Defendant dispensed meloxicam (another NSAID) pursuant to a prescription from PA LaRocca dated December 3, 2018. On December 22, 2018, the Defendants dispensed additional NSAIDs and muscle relaxers (i.e., nabumetone and cyclobenzaprine) pursuant to prescriptions issued by Ari Lerner, M.D. dated December 19, 2018. On January 16, 2019, the Defendants dispensed 90 Lidocaine Patches and Diclofenac Solution pursuant to prescriptions issued by PA Carlin on January 8, 2019, and which allowed for two refills of each pharmaceutical. Also on January 6, 2019, the Defendants refilled the prescription for meloxicam issued by PA LaRocca on December 3, 2018. On March 15, 2019, the Defendants dispensed a refill of the Diclofenac Solution pursuant to the January 8, 2019 prescription from PA Carlin, as well as 90 Lidocaine Patches, nabumetone, and cyclobenzaprine pursuant to prescriptions issued by Leonid Kol, M.D. ("Dr. Kol") on March 6, 2019. The prescription issued by Dr. Kol only called for 30 Lidocaine Patches, yet the Defendants dispensed and billed for 90 patches. On

April 23, 2019, the Defendants dispensed refills of 90 Lidocaine Patches and Diclofenac Solution pursuant to the January 8, 2019 prescription from PA Carlin, as well as refills of cyclobenzaprine and nabumetone pursuant to the March 6, 2019 prescriptions issued by Dr. Kol.

(vi) Insured FV was involved in a minor motor vehicle accident on July 20, 2019. She sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On August 2, 2019, the Defendants dispensed to the Insured 60 Lidocaine Patches, Diclofenac Solution, cyclobenzaprine, and naproxen pursuant to prescriptions issued by PA Carlin on July 30, 2019 – ten days post-accident. The prescriptions for naproxen, Lidocaine Patches, and Diclofenac Solution each allowed for two refills. The Defendants dispensed the refills of naproxen, Lidocaine, Patches, and Diclofenac Solution to the Insured on September 24, 2019 and December 17, 2019. The patient was also prescribed a heat pad which was dispensed by Defendants on August 2, 2019.

(vii) Insured LH was involved in a minor motor vehicle accident on August 27, 2019. She sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On September 7, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, naproxen and butalbital pursuant to prescriptions issued by PA Carlin on September 5, 2019 – nine days post-accident. The prescriptions for naproxen, Lidocaine Patches, and Diclofenac Solution each allowed for two refills. The Defendants dispensed the refills of naproxen and Lidocaine Patches to the Insured on November 27, 2019.

(viii) Insured VR was involved in a minor motor vehicle accident on September 5, 2019. She sought treatment at a No-Fault Clinic located at 2825 Third Avenue, Bronx, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On September 11, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, naproxen, and cyclobenzaprine pursuant to prescriptions issued by PA Carlin on September 10, 2019 – five days post-accident. The prescriptions for naproxen, Lidocaine Patches, and Diclofenac Solution each allowed for two refills. The Defendants dispensed the refills of naproxen, Lidocaine Patches, and Diclofenac Solution to the Insured on December 27, 2019. On January 3, 2020, the Defendants dispensed to the Insured oxycodone, celecoxib, docusate, and ondansetron pursuant to prescriptions issued by Dr. Seldes dated December 31, 2019.

(ix) Insured LM was involved in a minor motor vehicle accident on September 10, 2019. She sought treatment at a No-Fault Clinic located at 200 Madison Avenue, New York, New York where she came under the care of Dr. Goldenberg of Central Park PC. On October 15, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, naproxen, and cyclobenzaprine pursuant to prescriptions issued by PA Carlin on October 7, 2019. The prescriptions for naproxen, Lidocaine Patches, and Diclofenac Solution each allowed for two refills.

(x) Insured IC was involved in a minor motor vehicle accident on May 21, 2019. He sought treatment at a No-Fault Clinic located at 2 West 86th Street, New York, New York where she came under the care of Dr. Goldenberg and PA Carlin of Central Park PC. On May 28, 2019, the Defendants dispensed to the Insured 90 Lidocaine Patches, Diclofenac Solution, and naproxen pursuant to prescriptions issued by PA Carlin on May 24, 2019 – three days post-accident. The prescriptions each allowed for two refills. The Defendants dispensed refills of each medication on July 24, 2019.

199. The Defendants' egregious billing coupled with the fact that the Prescribing Providers failed to properly document – or even document at all – the prescriptions for Lidocaine Patches and Lidocaine 5% Ointment, or the Insureds' use of these medications, further indicates that there was no legitimate medical reason for the Prescribing Providers to prescribe large volumes of these medications to the Insureds, or for SMK Pharmacy to dispense such large volumes to the Insureds, particularly given the potential for adverse health effects.

200. The Defendants typically charged between $308.49 and $613.89 for a single Lidocaine 5% Ointment prescription and between $229.69 and $903.59 for a single prescription for Lidocaine Patches.

201. To-date, the Defendants, through SMK Pharmacy, have submitted over $1,288,400.00 in claims seeking reimbursement for Lidocaine 5% Ointment and Lidocaine Patches.

F. The Exploiting of Patients for Financial Gain Through the Illegal, Collusive Arrangements Among the Defendants, Prescribing Providers and Clinic Controllers

202. To effectuate the fraudulent scheme, the Defendants participated in illegal, collusive arrangements in which the Defendants steered the Clinic Controllers and the Prescribing Providers to routinely prescribe and direct prescriptions to SMK Pharmacy for a targeted set of

prescription drugs (i.e., the Fraudulent Topical Pain Products) to submit egregiously inflated charges to GEICO without regard for genuine patient care.

203. New York's statutory framework provides, among other things, that pharmacies and licensed medication professionals such as physicians and physician's assistants are prohibited from (i) "exercising undue influence" on a patient by promoting the sale of drugs so as to exploit the patient for the financial gain of the licensee or of a third party, and (ii) "directly or indirectly" giving, soliciting, receiving, or agreeing to receive any fee or other consideration to or from a third party in connection with the performance of professional services.

204. New York's statutory framework also specifically prohibits collusive arrangements between licensed physicians and pharmacies involving compounded or specially marked prescriptions. See Education Law § 6530(38) and § 6811(7). In fact, New York Education Law § 6811(7) makes such agreements criminal.

205. Here, the Defendants colluded with Prescribing Providers and Clinic Controllers associated with various No-Fault Clinics, which treat thousands of Insureds, to have the Prescribing Providers, prescribe, or purport to prescribe, the Fraudulent Pharmaceuticals, including the Fraudulent Topical Pain Products, and then to have those prescriptions directed to SMK Pharmacy which in turn permitted the Defendants to bill GEICO for large sums.

206. In furtherance of the scheme, the Defendants colluded with the Clinic Controllers and Prescribing Providers and caused the Prescribing Providers to intentionally prescribe, or purport to prescribe, the Fraudulent Topical Pain Products to patients of the No-Fault Clinics pursuant to the Defendants' fraudulent predetermined protocols, without regard for genuine patient care, without regard for cost and attention to fiscal responsibility, and often without regard for pharmacologic outcomes.

207. The purpose of the Defendants supplying the Prescribing Providers and Clinic Controllers with the pre-set stamps was so that the Prescribing Providers may repeatedly issue predetermined and/or medically unnecessary and formulaic prescriptions for the expensive Fraudulent Pharmaceuticals that SMK Pharmacy "specialized" in dispensing, including the Fraudulent Compounded Pain Creams they produced, in order to exploit the patients' No-Fault Benefits.

208. The Prescribing Providers prescribed, or purported to prescribe, the Fraudulent Topical Pain Products to patients of the No-Fault Clinics, and the Prescribing Provider and Clinic Controller steered those prescriptions to SMK Pharmacy, despite their knowledge that they were involved in illegal, collusive arrangements designed to exploit the patients for financial gain; that the Fraudulent Compounded Pain Creams were not customized or tailored to the individual needs of a particular patient; that the Fraudulent Topical Pain Products were often being prescribed and dispensed without regard to pharmacologic outcomes; that the Fraudulent Topical Pain Products were often prescribed with gross indifference to patient care and safety; the Fraudulent Topical Pain Products were prescribed and dispensed as a matter of course without any recommendation that patients first try over-the-counter products; and that the Fraudulent Topical Pain Products were prescribed without attention to cost and fiscal responsibility given that there are FDA-approved drugs available and appropriate for the particular patients at significantly less cost.

209. The Defendants, in collusion with the Prescribing Providers and Clinic Controllers, made sure the Insureds never had the option to use a pharmacy of their choosing and instead ensured the prescriptions for the Fraudulent Pharmaceuticals were directed to SMK Pharmacy, notwithstanding that (i) in many instances the Prescribing Providers and the patients were located

far from SMK Pharmacy in Rockaway Beach, New York; and (ii) there were countless other pharmacies located much closer to the Prescribing Providers and the patients.

210. The Prescribing Providers and Clinic Controllers directed the prescriptions for the Fraudulent Topical Pain Products to SMK Pharmacy because the prescriptions were solely issued because of the illegal, collusive arrangements among the Defendants, Prescribing Providers, and Clinic Controllers. Any prescriptions that may have been filled through other pharmacies was done so only to evade detection by GEICO of the fraudulent treatment protocol, or pursuant to a separate fraudulent scheme.

211. SMK Pharmacy purported to mail or deliver the Fraudulent Topical Pain Products directly to the patients at the No-Fault Clinics where the patients were purportedly being treated.

212. The Insureds were often given the Fraudulent Topical Pain Products by the front desk staff at the various No-Fault Clinics, in many cases, without even knowing that they were to receive one or more of the Fraudulent Topical Pain Products.

213. The Prescribing Providers had no legitimate medical reason to prescribe the Fraudulent Pharmaceuticals in large quantities to their patients.

214. The Prescribing Providers and the Clinic Controllers had no legitimate reason to direct the prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy rather than to a multitude of other pharmacies that were equally capable of dispensing the prescriptions and often more convenient to many of the patients.

215. The Prescribing Providers and Clinic Controllers would not have engaged in the illegal, collusive arrangements with the Defendants in violation of New York law, including using pre-set rubber stamps distributed by the Defendants, intentionally prescribing medically

unnecessary Fraudulent Topical Pain Products, and directing those prescriptions to SMK Pharmacy, unless they profited from their participation in the illegal scheme.

216. But for the payments of kickbacks, or other financial incentives from the Defendants, the Prescribing Providers would not have prescribed the Fraudulent Topical Pain Products and the Prescribing Providers and Clinic Controllers would not have directed the prescriptions to SMK Pharmacy.

217. The Defendants, Prescribing Providers, and Clinic Controllers affirmatively concealed the amounts paid for the kickbacks because such kickbacks are in violation of New York law.

218. Nevertheless, based on the circumstances surrounding the illegal, collusive, arrangements, the Defendants paid a financial kickback or provided other financial incentives, and the Prescribing Providers and Clinic Controllers received a financial kickback or other financial incentives, for each of the prescriptions for the Fraudulent Topical Pain Products that were dispensed by SMK Pharmacy.

219. Upon information and belief, the payment of such kickbacks was made at or near the time the prescriptions were issued.

G. The Fraudulent Billing the Defendants Submitted or Caused to be Submitted to GEICO

220. Every prescription product, whether a brand name or generic drug, has a designated national drug code ("NDC") – a unique 10-digit code that identifies the drug itself, the vendor of the drug and the quantity in which the drug was packaged. Each NDC number has an assigned Average Wholesale Price ("AWP").

221. Each NDC (and, thus, the AWP) for a particular drug product differs depending on both the particular supplier the drug is purchased from and the quantity in which the drug is

obtained. The same drug can have a different NDC number if it is purchased from a different supplier and/or in different quantities.

222. The maximum amount a healthcare provider may charge for a medically necessary prescription drug or product is based upon the drug's NDC number. With respect to compounded products, the maximum a healthcare provider may charge is based on each individual ingredient included in the compounded product and their corresponding NDC numbers and AWPs.

223. Pursuant to 12 N.Y.C.R.R. §§ 440.5(a) and (d) (the "Pharmacy Fee schedule"), for each brand name drug (or ingredient included in a compounded product) a provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 12% of the AWP, plus a single dispensing fee of $4.00.

224. For each generic drug (or ingredient included in a compounded product) the provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 20% of the AWP, plus a single dispensing fee of $5.00.

225. AWP is defined by 12 N.Y.C.R.R. § 440.2(a) as:

> "[t]he average wholesale price of a prescription drug as provided in the most current release of the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwer Health or any successor publisher, on the day a prescription drug is dispensed or other nationally recognized drug pricing index adopted by the Chair or Chair's designee."

226. When a pharmacist bills for dispensing prescription drugs (including compounded products), it must bill based on the actual NDC number (and the assigned AWP) for that drug or compound drug ingredient. It cannot use the NDC of the same ingredient available from a different supplier and/or purchased in different quantities in order to inflate the assigned AWP.

227. The Defendants solicited the Clinic Controllers and the Prescribing Providers to provide them with voluminous prescriptions for the pre-determined, formulaic Fraudulent

Compounded Pain Creams because the more ingredients contained in a compounded drug product, the more charges the Defendants may submit through SMK Pharmacy for dispensing the product.

228. The Defendants produced and dispensed the Fraudulent Compounded Pain Creams – which were produced in bulk by compounding multiple drug ingredients in nonsensical combinations with no proven efficacy – in order to inflate SMK Pharmacy's billing and maximize their profits.

229. Likewise, the Defendants solicited the Clinic Controllers and the Prescribing Providers to provided them with voluminous prescriptions for the other Fraudulent Topical Pain Products (i.e., Topical Diclofenac, Lidocaine 5% Ointment, and Lidocaine Patches) because the Defendants could readily buy these Fraudulent Topical Pain Products at low cost but bill GEICO and other New York No-Fault insurers inflated amounts based on egregiously high wholesale prices.

230. The Defendants intentionally targeted the Fraudulent Topical Pain Products, with extremely expensive "average wholesale prices," in order to inflate SMK Pharmacy's billing and maximize their profits.

231. The Defendants purported to provide the Fraudulent Pharmaceuticals, including the Fraudulent Topical Pain Products, directly to GEICO Insureds, and sought reimbursement directly from GEICO pursuant to executed "Assignment of Benefit" ("AOB") forms.

232. At times the Defendants failed to submit a delivery receipt confirming the Insureds actually received the medications billed to GEICO, or an executed AOB demonstrating that the Insureds in fact assigned their rights to No-Fault Benefits to the Defendants.

233. Moreover, the Defendants never submitted their wholesale purchase invoices demonstrating (i) how much the Defendants actually paid the supplier for the Fraudulent

Pharmaceuticals, including the ingredients contained in the Fraudulent Compounded Pain Creams, and (ii) whether the Defendants actually purchased the Fraudulent Pharmaceuticals or the ingredients contained in the Fraudulent Compounded Pain Cream under the particular NDC numbers used in the billing, representing purchases from a particular supplier in a particular quantity.

234. With respect to the Fraudulent Pharmaceuticals, SMK Pharmacy never actually paid the "average wholesale price" of the products it dispensed or purported to dispense, and in particular never paid the targeted and egregious average wholesale price for the Fraudulent Topical Pain Products, because it is not a true representation of actual market price and is far above the actual acquisition cost of the drug products themselves.

235. Nevertheless, the Defendants billed GEICO and other No-Fault insurers egregious amounts far surpassing both their actual acquisition costs as well as the costs of a wide variety of other medications that are FDA-approved and proven effective.

H. The Defendants' Submission of Fraudulent NF-3 Forms to GEICO

236. To support the fraudulent charges, statutorily prescribed claim forms for No-Fault Benefits consistently have been submitted to GEICO by and on behalf of SMK Pharmacy seeking payment for the pharmaceuticals for which it is ineligible to receive payment.

237. These forms, including NF-3 forms, HCFA-1500 forms and other supporting records that the Defendants submitted or caused to be submitted to GEICO, were false and misleading in the following material respects:

i. The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Fraudulent Pharmaceuticals were medically necessary and intended for genuine patient care. In fact, the Fraudulent Pharmaceuticals were medically unnecessary and prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit patients for financial gain, without regard for genuine patient care;

ii. The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Defendants were in compliance with all material licensing requirements and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Defendants did not comply with all material licensing requirements in that the Defendants participated in illegal, collusive relationships in which the Defendants steered the Prescribing Providers and Clinic Controllers to direct illegal prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy in exchange for unlawful kickbacks and other financial incentives;

iii. The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Defendants were in compliance with all material licensing requirements and, therefore, were eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Defendants did not comply with all material licensing requirements in that the dispensed the Fraudulent Pharmaceuticals pursuant to illegal, invalid, duplicitous and formulaic prescriptions;

iv. The NF-3 forms, HCFA-1500 forms and other supporting records uniformly misrepresented to GEICO that the Defendants were in compliance with all material licensing requirements and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Defendants did not comply with all material licensing requirements in that the Defendants intentionally targeted a specific set of pharmaceutical products that they could acquire at low cost and dispense in large volumes to Insureds at egregious charges, in place of other effective, less costly pharmaceuticals; and

v. The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Defendants were in compliance with all material licensing requirements and, therefore, were eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Defendants did not comply with all material licensing requirements in that they engaged in illegal bulk compounding by producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering SMK Pharmacy ineligible to receive reimbursement for No-Fault Benefits.

I. The Defendants' Fraudulent Concealment and GEICO's Justifiable Reliance

238. The Defendants are legally and ethically obligated to act honestly and with integrity

in connection with the provision of pharmaceutical products to Insureds and the billing they submit or cause to be submitted to GEICO seeking reimbursement for these products.

239. To induce GEICO to promptly pay the charges for the Fraudulent Compounded Drugs, the Defendants have gone to great lengths to systematically conceal their fraud.

240. Specifically, the Defendants knowingly have misrepresented and concealed facts in an effort to prevent discovery that (i) the Fraudulent Pharmaceuticals were prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care; (ii) the Defendants were involved in collusive kickback arrangements with the Prescribing Providers and Clinic Controllers designed to generate voluminous prescriptions solely to maximize the billing submitted to GEICO and other New York insurance companies; and (iii) the Defendants engaged in illegal bulk compounding by producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements

241. The Defendants also billed for the Fraudulent Pharmaceuticals based on purported prescriptions from multiple Prescribing Providers operating from multiple No-Fault Clinics in order to reduce the amount of billing based on any single licensee.

242. The billing and supporting documentation submitted by the Defendants for the Fraudulent Pharmaceuticals, when viewed in isolation, does not reveal its fraudulent nature.

243. The Defendants have hired law firms to pursue collection of the fraudulent charges from GEICO and other insurers. These law firms routinely file expensive and time-consuming litigation against GEICO and other insurers if the charges are not promptly paid in full. In fact, SMK Pharmacy continues to have legal counsel pursue collection against GEICO and other insurers without regard for the fact that SMK Pharmacy has been engaged in fraud.

244. The Defendants' continued collection efforts through numerous, separate collection proceedings is an essential part of their fraudulent scheme since they know it is impractical for a no-fault arbitrator or civil court judge in a single no-fault arbitration or civil court proceeding, typically involving a single bill, to uncover or address the Defendants' large scale, complex fraud scheme involving the prescription and dispensing of fraudulent pharmaceutical to hundreds of patients across numerous different No-Fault Clinics located throughout the New York metropolitan area.

245. GEICO is under statutory and contractual obligations to promptly and fairly process claims within 30 days. The facially-valid documents that were submitted to GEICO in support of the fraudulent charges at issue, combined with the material misrepresentations described above, were designed to and did cause GEICO to rely upon them. As a result, GEICO has incurred damages of approximately $1,184,700.00 representing payments made by GEICO based upon the fraudulent charges submitted by the Defendants, which damages are to be trebled under 18 U.S.C. § 1962(c)), et al. to $3,554,100.00.

246. Based upon the Defendants' material misrepresentations and other affirmative acts to conceal their fraud from GEICO, GEICO did not discover and could not reasonably have discovered that its damages were attributable to fraud until shortly before it filed this Complaint.

THE FIRST CLAIM FOR RELIEF
Against All Defendants
(Declaratory Judgment – 28 U.S.C. §§ 2201 and 2202)

247. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

248. There is an actual case in controversy between GEICO and SMK Pharmacy, Burlak, Kassman, Volman, and Field regarding approximately $1,926,600.00 in fraudulent billing

for the Fraudulent Pharmaceuticals that the Defendants submitted or caused to be submitted to GEICO through SMK Pharmacy.

249. SMK Pharmacy has no right to receive payment for any pending bills submitted to GEICO because SMK Pharmacy billed for pharmaceutical products that were medically unnecessary and prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care.

250. SMK Pharmacy has no right to receive payment for any pending bills submitted to GEICO because the Defendants participated in illegal, collusive relationships in which the Defendants steered the Prescribing Providers and Clinic Controllers to direct illegal prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy in exchange for unlawful kickbacks and other financial incentives.

251. SMK Pharmacy has no right to receive payment for any pending bills submitted to GEICO because the Defendants made and continue to make false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for the Fraudulent Pharmaceuticals dispensed by SMK Pharmacy pursuant to the illegal, invalid, duplicitous, and formulaic prescriptions.

252. SMK Pharmacy has no right to receive payment for any pending bills submitted to GEICO because the Defendants intentionally targeted a specific set of pharmaceutical products that they acquired at low cost and had SMK Pharmacy dispense in large volumes to Insureds at egregious charges, in place of other effective, less costly pharmaceuticals solely for financial gain in violation of law.

253. SMK Pharmacy has no right to receive payments for any pending bills submitted to GEICO because the Defendants engaged in illegal bulk compounding by specializing in

producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault Benefits.

254. The Defendants, including SMK Pharmacy, violated New York State regulatory and licensing requirements, rendering the pharmacy ineligible to receive reimbursement for No-Fault Benefits.

255. Accordingly, GEICO requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, declaring that Defendants have no right to receive payment for any pending bills submitted to GEICO through SMK Pharmacy.

THE SECOND CLAIM FOR RELIEF
Against Burlak, Kassman, Volman, and Field
(Violation of RICO, 18 U.S.C. § 1962(c))

256. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

257. SMK Pharmacy is an ongoing "enterprise", as that term is defined in 18 U.S.C. § 1961(4), that engages in activities which affect interstate commerce.

258. Burlak, Kassman, Volman, and Field knowingly conducted and/or participated, directly or indirectly, in the conduct of SMK Pharmacy's affairs through a pattern of racketeering activity consisting of repeated violations of the federal mail fraud statute, 18 U.S.C. § 1341, based upon the use of the United States mails to submit or cause to be submitted thousands of fraudulent charges on a continuous basis for over four years, seeking payments that SMK Pharmacy was not eligible to receive under the No-Fault Laws because: (i) the billed-for services were not medically necessary and/or were the product of predetermined fraudulent protocols designed to exploit the

patients for financial gain, without regard for genuine patient care; (ii) the Defendants participated in illegal, collusive relationships in which the Defendants steered the Prescribing Providers and Clinic Controllers to direct illegal prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy in exchange for unlawful kickbacks and other financial incentives; (iii) the billed-for services were the product of illegal, invalid, duplicitous and formulaic prescriptions; (iv) the Defendants intentionally targeted a specific set of pharmaceutical products that they could acquire at low cost and dispense in large volumes to Insureds with egregious charges, in place of other effective, less costly pharmaceuticals solely for financial gain in violation of law; and (v) SMK Pharmacy engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements, rendering it ineligible to receive reimbursement for No-Fault Benefits. The fraudulent bills and corresponding mailings submitted to GEICO that comprise the pattern of racketeering activity identified through the date of this Complaint are described, in substantial part, in the chart annexed hereto as Exhibit "1".

259. SMK Pharmacy's business is racketeering activity, inasmuch as the enterprise exists for the purpose of submitting fraudulent charges to insurers. The predicate acts of mail fraud are the regular way in which Burlak, Kassman, Volman, and Field operated SMK Pharmacy, inasmuch as SMK Pharmacy never was eligible to bill for or collect No-Fault Benefits, and acts of mail fraud therefore were essential in order for SMK Pharmacy to function. Furthermore, the intricate planning required to carry out and conceal the predicate acts of mail fraud implies a threat of continued criminal activity, as does the fact that the Defendants continue to attempt collection on the fraudulent billing submitted through SMK Pharmacy to the present day.

260. SMK Pharmacy is engaged in inherently unlawful acts inasmuch as its very existence is an unlawful act, considering that it was created to exploit the New York "No-Fault" insurance system; engage in illegal, collusive arrangements involving prescriptions for the Fraudulent Pharmaceuticals, including Fraudulent Compounded Pain Creams; and bill pursuant to predetermined fraudulent protocols solely to financially enrich the Defendants. These inherently unlawful acts are taken by SMK Pharmacy in pursuit of inherently unlawful goals – namely, the theft of money from GEICO and other insurers through fraudulent No-Fault billing.

261. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $1,184,700.00 pursuant to the fraudulent bills submitted by the Defendants through SMK Pharmacy.

262. By reason of its injury, GEICO is entitled to treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c), and any other relief the Court deems just and proper.

THE THIRD CLAIM FOR RELIEF
Against All Defendants
(Common Law Fraud)

263. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

264. The Defendants intentionally and knowingly made false and fraudulent statements of material fact to GEICO and concealed material facts from GEICO in the course of their submission of thousands of fraudulent charges seeking payment for the Fraudulent Pharmaceuticals under the name of SMK Pharmacy.

265. The false and fraudulent statements of material fact and acts of fraudulent concealment include: (i) in every claim, the representation that the billed-for services were

medically necessary and properly billed when in fact the billed-for services were not medically necessary and/or were the product of predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care; (ii) in every claim, the representation that SMK Pharmacy acted in accordance with material licensing requirements and, therefore, was eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the Defendants participated in illegal, collusive relationships in which the Defendants steered the Prescribing Providers and Clinic Controllers to direct illegal prescriptions for the Fraudulent Pharmaceuticals to SMK Pharmacy in exchange for unlawful kickbacks and other financial incentives; (iii) in every claim, the representation that SMK Pharmacy acted in accordance with material licensing requirements and, therefore, was eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the billed-for services were the product of illegal, invalid, duplicitous, and formulaic prescriptions; (iv) in every claim, the representation that SMK Pharmacy acted in accordance with material licensing requirements and, therefore, was eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the Defendants intentionally targeted a specific set of pharmaceutical products that they could acquire at low cost and dispense in large volumes to Insureds with inflated charges, in place of other effective, less costly pharmaceuticals solely for financial gain in violation of law; and (v) in every claim, the representation that SMK Pharmacy acted in accordance with materials licensing requirements and, therefore, was eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact SMK Pharmacy engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent

Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements.

266. The Defendants intentionally made the above-described false and fraudulent statements and concealed material facts in a calculated effort to induce GEICO to pay charges submitted through SMK Pharmacy that were not compensable under the No-Fault Laws.

267. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $1,184,700.00 pursuant to the fraudulent bills submitted, or caused to be submitted, by the Defendants through SMK Pharmacy.

268. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles GEICO to recover punitive damages.

269. Accordingly, by virtue of the foregoing, GEICO is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

THE FOURTH CAUSE OF ACTION
Against All Defendants
(Unjust Enrichment)

270. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

271. As set forth above, the Defendants have engaged in improper, unlawful, and/or unjust acts, all to the harm and detriment of GEICO.

272. When GEICO paid the bills and charges submitted by or on behalf of SMK Pharmacy for No-Fault Benefits, it reasonably believed that it was legally obligated to make such payments based on the Defendants' improper, unlawful, and/or unjust acts.

273. The Defendants have been enriched at GEICO's expense by GEICO's payments, which constituted a benefit that the Defendants voluntarily accepted and profited from, as a result of, among other things, the payments received, notwithstanding their improper, unlawful, and unjust fraudulent billing scheme.

274. The Defendants' retention of GEICO's payments violates fundamental principles of justice, equity and good conscience.

275. By reason of the above, the Defendants have been unjustly enriched in an amount to be determined at trial, but in the approximate amount of $1,184,700.00.

WHEREFORE, Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company demand that a judgment be entered in their favor and against the Defendants, as follows:

A. On the First Claim for Relief against the Defendants, a declaration pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that SMK Pharmacy has no right to receive payment for any pending bills, amounting to approximately $1,926,600.00 submitted to GEICO;

B. On the Second Claim For Relief against Burlak, Kassman, Volman, and Field compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $1,184,700.00, together with treble damages, punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

C. On the Third Claim for Relief against Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $1,184,700.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

D. On the Fourth Claim for Relief against Defendants, a recovery in favor of GEICO in an amount to be determined at trial but approximately $1,184,700.00 together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper.

Dated: Uniondale, New York
June 8, 2021

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